Focused on

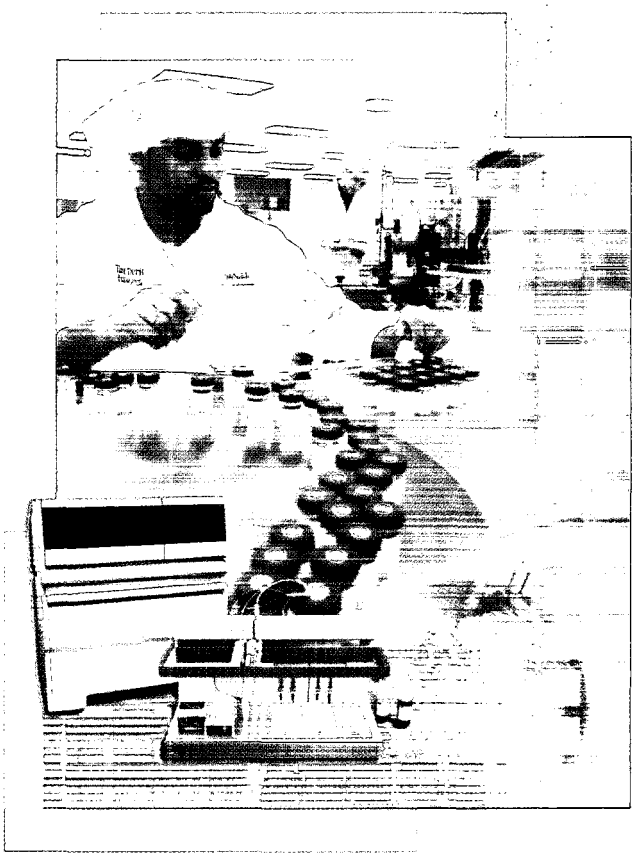
innovative solutions

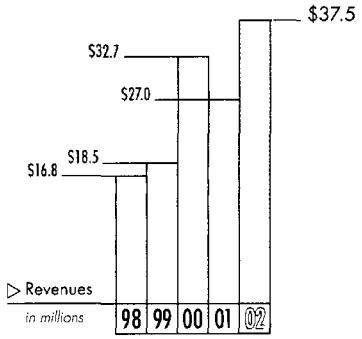
the clinical management of cancer

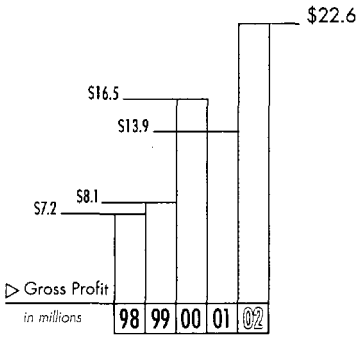
TRIPATH IMAGING, INC.

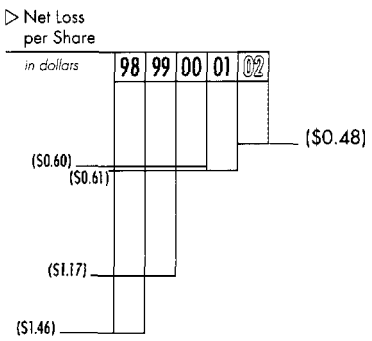
2002 Annual Report

Redefining the early detection and clinical management of cancer









TriPath Imaging creates solutions that redefine the early detection and clinical management of cancer. Specifically, we develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We were incorporated in October 1996 as AutoCyte, Inc. and changed our name to TriPath Imaging, Inc. in September 1999 in connection with the merger of AutoCyte, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed and marketed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We have created new opportunities and applications for our proprietary technology by applying recent advances in genomics, biology, and informatics to develop new molecular diagnostic and pharmacogenomic products and services for malignant melanoma and cancers of the cervix, breast, ovary, and colon and rectum.

American women have about a one-in-three lifetime risk of developing invasive cancer

American women have about a one-in-three lifetime risk of developing invasive cancer. It is estimated that in 2003 alone, approximately 658,800 women will be newly diagnosed with cancer and an estimated 270,600 women will succumb to the disease. Melanoma and cancers of the cervix, breast, ovary, and colon and rectum will likely account for over one half of all cancers diagnosed in women in 2003. We are creating solutions to redefine the early detection and clinical management of these diseases.

SELECTED FINANCIAL DATA

($ in thousands, except per share data)	Year Ended December 31,				
Statement of Operating Data[3]	1998	1999	2000	2001	2002
Revenues	$ 16,849	$ 18,466	$ 32,652	$ 27,017	$ 37,485
Gross profit	7,155	8,098	16,529	13,921	22,563
Research and development[1]	15,969	12,258	9,629	9,259	11,247
Selling, general and administrative	25,408	17,724	23,867	27,346	29,798
Operating loss	(37,307)	(33,251)	(16,967)	(22,684)	(18,482)
Net loss	$(35,271)	$(32,557)	$(17,369)	$(21,680)	$(18,064)
Net loss per share (basic and diluted)[2]	$ (1.46)	$ (1.17)	$ (0.60)	$ (0.61)	$ (0.48)
Weighted-average shares outstanding[3]	24,098	27,819	29,137	35,467	37,438
Balance Sheet Data[3]					
Cash, cash equivalents and short-term investments	$ 28,941	$ 13,962	$ 54,340	$ 55,976	$ 32,571
Working capital	32,553	17,338	62,316	62,898	38,837
Total assets	68,176	58,874	97,471	96,748	73,951
Long term obligations	2,051	1,117	3,760	5,001	220
Total stockholders' equity	$ 55,075	$ 47,025	$ 80,774	$ 77,291	$ 59,177

(1) Includes regulatory expenses.

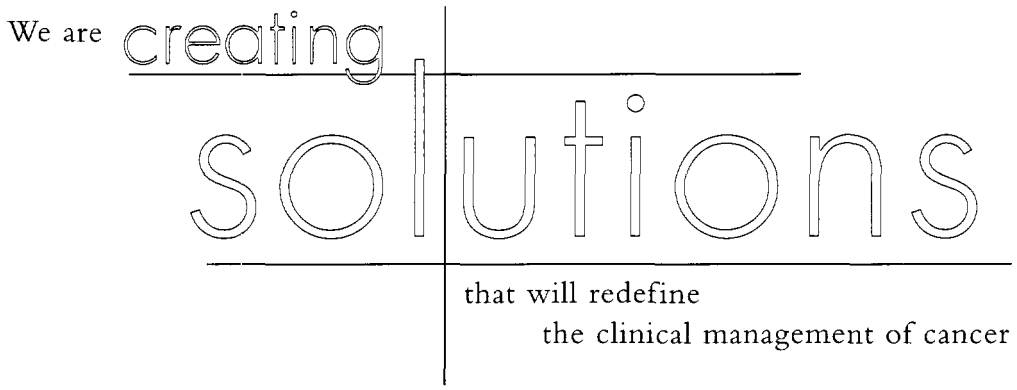
(2) See Note 2 of our notes to consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2002 for information concerning the computation of net loss per share and shares used in computing net loss per share.

(3) The selected consolidated financial data has been restated to reflect the pooling transaction that occurred on September 30, 1999.

Statements in this Annual Report that are not strictly historical statements constitute forward-looking statements which involve risks and uncertainties that could cause actual results and outcomes to differ materially from what is expressed in those forward-looking statements. Important factors that may affect our future operating results include, without limitation: we may not receive revenues when or in the amounts anticipated; we may not achieve profitability when anticipated or at all; our products may not receive FDA approval and/or clearance when expected, if at all; our clinical trials may not demonstrate clinical efficacy of our products; our products may not be accepted by the market to the degree expected, if at all; we may be unable to successfully initiate and manage collaborations and other commercial relationships; changes in general economic conditions and in the healthcare industry could adversely affect our business; competition and competitive pricing pressures could cause our revenues and gross margins to decrease; and other risks described in our filings with the Securities and Exchange Commission, including those described in the section entitled "Factors Affecting Future Operating Results" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

→ *At TriPath Imaging, we remain focused on creating solutions that will redefine the early detection* and clinical management of cancer. As an established competitor in the cervical cancer screening market, we are using our proprietary technologies to create an array of products that are designed to improve the early detection, diagnosis, staging, treatment selection, and monitoring of melanoma and cancers of the cervix, breast, ovary, and colon and rectum. This is truly an important goal, as American women have about a one-in-three lifetime risk of developing invasive cancer. It is estimated that in 2003 alone, approximately 658,800 women will be newly diagnosed with cancer and an estimated 270,600 women will succumb to the disease. Melanoma and cancers of the cervix, breast, ovary, and colon and rectum will likely account for over one half of all cancers diagnosed in women in 2003, and our focus is on improving the outcomes from these diseases.

To this end, in 2001 we created TriPath Oncology. While the sale of components of our integrated solution for cervical cancer screening still generates approximately 90% of our current revenues, we believe TriPath Oncology will create significant new opportunities and applications for our proprietary technology in the future. Together with Becton, Dickinson and Company ("BD"), we are applying recent advances in genomics, biology, and informatics to develop new molecular diagnostic products and services that will address unmet clinical needs in the early detection and clinical management of our targeted cancers.



To achieve our long-term goals, we set two key operating objectives for 2002: first, to drive our commercial operations segment to break even in the fourth quarter and second, to achieve significant and tangible progress toward developing and commercializing our molecular diagnostic products. I am pleased to report that we achieved both objectives.

Key Objective Achieved ▷ Commercial Operations Segment Reached Break Even in Fourth Quarter

Three years ago we redefined our business strategy and goals for our commercial operations segment to focus on growing revenues, driving margin and, thereby, generating cash to create the infrastructure to support the commercial introduction of an expanding pipeline of products. We believed that, in so doing, we would transform the company. And we did. Today, our mission is driven by the market and not solely by our technology. In fact, nearly half of our approximately 270 employees are now engaged directly in customer sales and service. As a result, our current product portfolio, specifically our integrated solution for cervical cancer screening, was repositioned for commercial success and in 2002, our commercial operations delivered, achieving break-even results in the fourth quarter of 2002.

"In short, we reinvented the economics of our business and created a clear pathway to profitability."

Paul R. Sohmer, M.D.
President, Chief Executive Officer and Chairman of the Board

THE YEAR IN REVIEW

- We achieved break-even for our commercial operations segment in the fourth quarter of 2002 and increased revenues by 39% over 2001
- Worldwide sales of reagents and disposables increased 127% and our gross profit increased to over 60%
- Our international business grew over 90% last year and we made great strides in the Canadian marketplace
- A CPT code for the combined use of our SurePath and FocalPoint products was issued
- We introduced our first molecular diagnostic product, an analyte specific reagent for a laboratory developed assay for melanoma
- We are on track to introduce additional analyte specific reagents in 2004
- We created a model for the early commercialization of other molecular diagnostic products
- We completed marker discovery for cancer of the cervix, breast, and ovary
- We adapted our proprietary imaging platform to support our molecular diagnostic programs and leveraged this platform to develop a new collaboration that further expands our product and commercial opportunities

Among our strategic achievements, we aggressively shifted our product sales mix from capital equipment to higher margin reagent and disposable sales, we increased net realized revenue per test by phasing out third party lease arrangements and improving pricing among new customers, we grew our base business by adding new customers, and we accelerated growth in reagent and disposable sales from pre-existing customers.

While we believe that there may be a cost advantage inherent to the manufacture of some of our products relative to the competition, we have sought to aggressively manage our costs to protect this potentially significant competitive advantage. In early 2002, we reorganized our manufacturing operations and added management expertise in Lean Manufacturing. We are also incorporating process improvement methodologies to eliminate non-value-adding activities, to reduce costs and to improve quality. These actions contributed to the improved financial performance of our commercial operations segment during the year.

In 2002, we recorded revenues of $37.5 million, a 39% increase from 2001. Most striking, however, was the fact that worldwide sales of reagents and disposables increased 127% to 66% of revenues as compared to just 40% of revenues in 2001. As a result, our gross profit grew from $13.9 million, or 52% of sales in 2001, to $22.6 million, or 60% of sales in 2002. In fact, our incremental revenues of $10.5 million generated an incremental gross profit of $8.7 million, a gross margin of 83% on incremental revenues. This drove our commercial operations segment to break even in the fourth quarter, dramatically reduced our cash burn rate and positioned our commercial operations to generate positive cash flow in the future. In short, we reinvented the economics of our business and created a clear pathway to profitability.

Building Our Business

As we build our business, we have had a particular focus on generating sales from academic centers of excellence, as well as regional and hospital laboratories, and integrated provider networks here in the U.S. Our "franchise" among our academic centers of excellence was further strengthened in 2002 through the addition of high profile opinion leaders to our customer list. We also continued to encourage the presentation and publication of independent investigators' experience with our products, which resulted in 32 papers describing the performance of our products being presented at the 2002 Scientific Meeting of the American Society of Cytopathology.

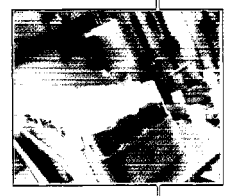
OUR MISSION IS MARKET DRIVEN

We created our Commercial Operations segment to drive revenue and margin from our commercially available product portfolio, to generate cash and to create the infrastructure necessary to support the commercial introduction of an expanding pipeline of products.

We have introduced a market driven approach to all of our activities; our mission is driven by the market and not solely by our technology. As a result, we have repositioned our current product portfolio, specifically our integrated solution for cervical cancer screening, for commercial success. Supporting our marketing efforts are over 130 employees who are now engaged directly in customer sales and service.

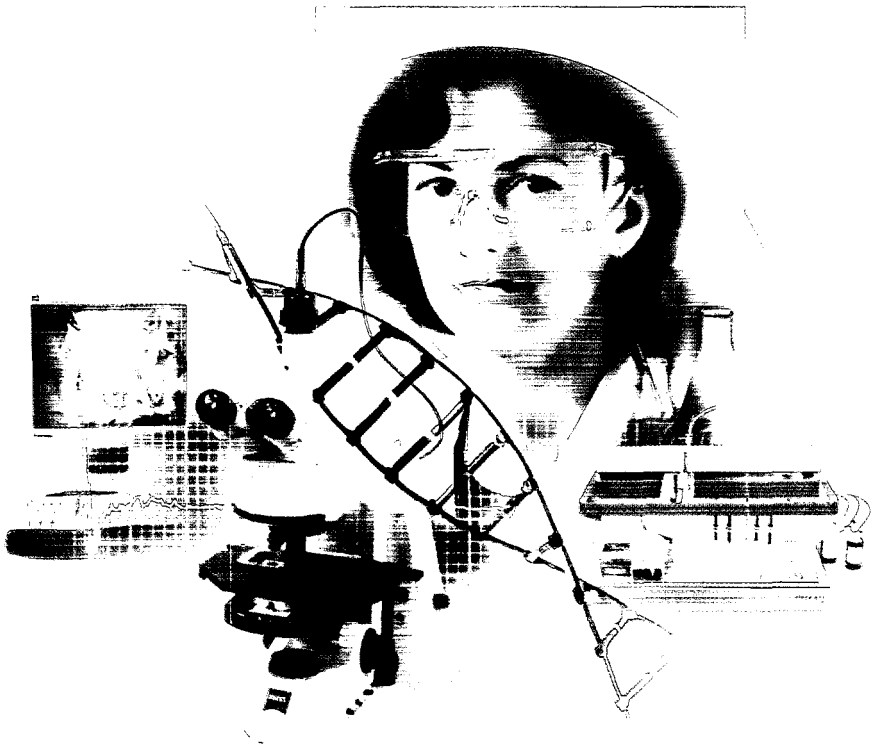
In 2002, we gained over 120 new PrepStain customers, 73 here in the U.S., bringing the total to nearly 450 customers worldwide. We added 29 new FocalPoint customers bringing the total to nearly 130 worldwide. We also added 19 new SlideWizard customers bringing the total to nearly 160 worldwide and, having done so, have set the stage for the future introduction of our tissue based molecular diagnostic products.

We will leverage the recognition, relationships, and infrastructure that we have developed to market and sell our i^3 Series cervical cancer screening product line and continue to build upon our sales, marketing and operations capabilities to further establish our competitive strengths in the marketplace and create a platform from which to commercialize our expanding pipeline of products.



Ray W. Swanson,
Senior Vice-President, Commercial Operations

Our strong growth in the U.S. was complemented by increased penetration within targeted international markets such as Canada, Germany, Switzerland, Belgium and the Netherlands. Our international business grew by over 90% in 2002 and now accounts for 32% of our worldwide sales. Revenues derived from international sales of reagents and disposables increased by over 130%. Our experience in Canada is particularly noteworthy. We believe that our products account for in excess of 95% of all liquid-based cytology tests and nearly 30% of all cervical cytology tests performed in Canada as the result of our exclusive agreements with its largest commercial laboratories.



Work-in-Progress

While we have made significant progress both strategically and financially to position our commercial operations segment for future growth, we have many projects in the works that should further strengthen our competitive position.

We are currently sponsoring two multi-center clinical trials designed to collect data to support Pre-Market Approval ("PMA") supplement applications to the FDA and are actively engaged in discussions regarding the design of a third study to gain FDA approval for human papilloma virus testing on cells collected in our SurePath Test Pack.

Our alternative sample collection device clinical trials are well underway and will test the safety and efficacy of alternative sample collection devices, including the cervical brush and cervical spatula, with our SurePath Test Pack. A clinical trial for our FocalPoint GS is also progressing. Introduced outside of the U.S. in late

FINANCIAL HIGHLIGHTS

- **Revenues of $37.5 million, an increase of 39% over 2001**
- **Reagent and disposable sales accounted for 66% of total, up from 44% in 2001**
- **Gross profit increased from 52% to 60%**
- **U.S. sales of reagents and disposables increased 120% over 2001; worldwide increase was 127%**
- **International business grew 90% in 2002, accounts for 32% of total**

2000, the FocalPoint GS integrates our SlideWizard technology into the screening process and automates the microscopic analysis of cervical smears designated for further review by the FocalPoint Slide Profiler. Having gone the extra step of receiving a binding agreement for our investigational plan, plus the fact that to date over 2 million slides have been screened using the FocalPoint GS outside of the U.S., we are confident of a positive outcome to this trial. We hope to make submissions to the FDA based on the data collected in both these trials on or about mid-2003.

We are also actively engaged with the FDA and Digene Corporation regarding the collection of additional data to support FDA approval for human papilloma virus testing using the Digene Hybrid Capture II HPV test on cells collected in our SurePath Test Pack. We will lead this process going forward and hope to submit these data to the FDA in the second half of 2003.

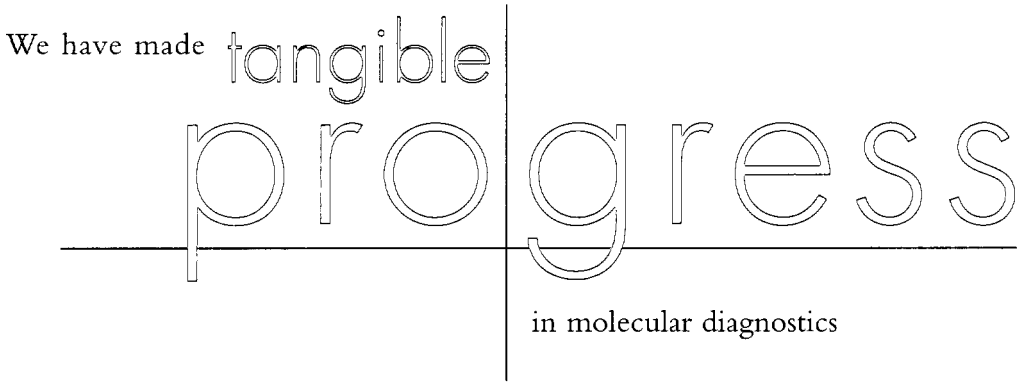
Second Key Objective Achieved > Tangible Progress in Molecular Diagnostics

TriPath Oncology is the development engine of one of the broadest based gene discovery programs in cancer diagnostics today. Through collaborative relationships with BD and Millennium Pharmaceuticals, Inc. we have created a unique approach to the development of molecular diagnostic products and services. Our approach comprehends the clinical and market directed identification and validation of novel molecular markers, the development of an assay format that will facilitate adoption by clinical laboratories, the development of clinical instrumentation that will permit multiple and quantitative gene and protein expression analysis within cells and a strategy for the early commercialization of resulting products and services.

This strategy leverages key assets of TriPath Imaging as well as our collaborative partners to expand our product pipeline and to create new opportunities for commercial success. These assets include the commercial rights to novel molecular markers for melanoma and cancers of the cervix, breast, ovary, and colon and rectum to which we gained access through our relationship with BD, our proprietary and commercially tested image analysis platform, a newly created world-class team of scientists with expertise in rare reagent and assay development, and the recognition, relationships, and infrastructure that we have developed to market and sell our i^3 Series cervical cancer screening products.

With these assets in place, TriPath Oncology delivered tangible progress in 2002.

We recently introduced our first molecular diagnostic product, an analyte specific reagent to be used in a laboratory developed assay for malignant melanoma. In so doing, we achieved a major milestone and established a model for the early commercialization of our molecular diagnostic products. We introduced our analyte specific reagent for melanoma through a collaborative agreement with AmeriPath, Inc., the leading provider of skin pathology services in the U.S. AmeriPath developed and validated a "home brew" assay utilizing our gene-based detection probe and our SlideWizard imaging and telepathology platform. AmeriPath will initially offer the melanoma assay at its Center for Advanced Diagnostics facility located in Orlando, Florida. This agreement further contemplates the initiation of additional research studies by the parties to more broadly assess the clinical significance of the melanoma assay.



Having prioritized our development efforts, we focused our resources on the commercial development of tests for cancers of the cervix, breast, and ovary, where our progress to date has been exciting, where the potential clinical and economic value is clear, and where we can leverage our commercial presence and historical commitment to improving the clinical management of women's health. We completed marker discovery for each of these clinical targets in the third quarter of 2002 and immediately initiated development work and pre-clinical validation studies for assays for staging of cervical and breast cancer. The reagents will incorporate, for each targeted cancer, a combination of markers that has been optimized to meet our clinical and commercial specifications. These achievements put us on track to introduce additional analyte specific reagents by the end of 2004.

It is important to note that our marker discovery programs are all driven by clinical specifications developed from an ongoing analysis of the current standards of care for melanoma and cancers of the cervix, breast, ovary, and colon and rectum. From these analyses, we have identified areas of clinical need and, therefore, market opportunity. Our product development strategy comprehends minimal disruption of laboratory workflow and current practice. We are designing our products to change the clinical practice of medicine, not the laboratory

A UNIQUE APPROACH TO THE DEVELOPMENT OF MOLECULAR DIAGNOSTIC PRODUCTS AND SERVICES

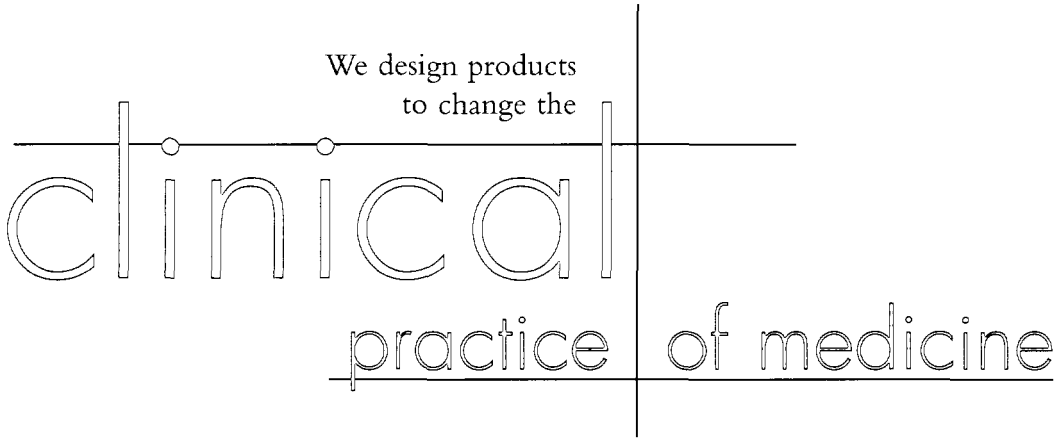
We are the development and commercial engine of one of the broadest based gene discovery programs in cancer diagnostics in the world today. TriPath Oncology was created in 2001 to manage the development of products resulting from our collaboration with Becton, Dickinson and Company ("BD"). The products developed by TriPath Oncology incorporate genomic and protein molecular markers identified through discovery research performed at Millennium Pharmaceuticals, Inc. under its research and development agreement with BD. We recently introduced our first product, an analyte specific reagent for a laboratory-developed assay for melanoma. We are currently developing molecular diagnostic products for cancer of the cervix, breast, ovary, and colon and rectum.

Our product strategy combines the sensitivity and specificity of molecular markers with the power of quantitative cellular image analysis to create molecular signatures, and to utilize these molecular signatures for detecting cancer at the earliest possible stage, providing individualized predictive and prognostic information, guiding treatment selection, and predicting disease progression. Our core products incorporate genomic and proteomic markers identified through discovery research that was driven by clinical specifications which we believe reflect current unmet clinical needs and, therefore, represent significant commercial opportunity. Our proprietary imaging platform produces high-resolution digital images of cells and tissue stained with our molecular markers and applies innovative, proprietary algorithms to analyze the digital slides providing quantitative measurement for each molecular marker on the slide. All of our assays are being developed in universally accepted, standardized formats and on commercially available laboratory platforms.

Johnny D. Powers, Ph.D.
Vice-President and General Manager, TriPath Oncology

practice of medicine. We are employing a strategy for early commercialization that includes the initial introduction of analyte specific reagents to be used in laboratory-developed assays through collaborative relationships with laboratory partners.

Finally, we have adapted our proprietary imaging platform to facilitate assay development and, in so doing, created a prototype that can be readily adapted for commercial use to support our molecular diagnostic programs. We expect to leverage the recognition, relationships, and infrastructure that we have developed to market and sell our i^3 Series cervical cancer screening product line to commercialize our molecular diagnostic products. In effect, the infrastructure we have built to sell our cervical cancer screening product line will serve as a conduit for our molecular diagnostic products.



New Opportunities for Growth

Given our market strategy to date, the growth we have enjoyed in our domestic business has primarily resulted from sales generated among academic centers of excellence, regional and hospital laboratories, and integrated provider networks. Nevertheless, we believe that our product strategy clearly mirrors the critical imperatives articulated by the larger commercial laboratories: 1) continued earnings growth from cervical cancer screening; 2) anatomic pathology as a strategic opportunity, and, 3) molecular diagnostics. We also believe that the cost advantages associated with the use of our products, our integrated system, and our portfolio of imaging products should be uniquely compelling to the large commercial laboratories.

To this end, we were pleased to announce in March of 2003, that we had entered into a collaboration agreement with Quest Diagnostics, the largest provider of diagnostic laboratory testing in the U.S. Under the terms of the agreement, Quest will be begin offering our i^3 Series integrated solution for cervical cancer screening, including our SurePath Test Pack, our PrepStain Slide Processor, and our FocalPoint Slide Profiler in selected locations. Quest will evaluate the i^3 Series relative to its immediate and future needs for cervical cancer screening. In addition, Quest has installed our Tele-pathology system in two locations and is currently evaluating various aspects of the system's utility. We believe that our products will create significant value for Quest and its customers.

We are also leveraging our proprietary imaging technology to develop new collaborations to expand our commercial opportunities. In early 2003, we entered into an agreement with Bristol-Meyers Squib Company to provide quantitative tissue-based image analysis in support of their oncology therapeutics programs targeted at treating epithelial cancers including cancers of the cervix, breast, and colon. We are utilizing our SlideWizard image analysis platform and proprietary software applications to provide a quantitative assessment of tumor expression levels from tissue samples provided by Bristol-Myers Squibb for patients enrolled in a Phase I clinical trial. The data generated by our work will be used to evaluate patient response across varied dosing levels based on changes in tumor marker expression levels, both before and after treatment. We believe that this type of collaboration could define new commercial opportunities for our technology and, in particular, tie us into the future development and commercialization of specific therapeutic agents.

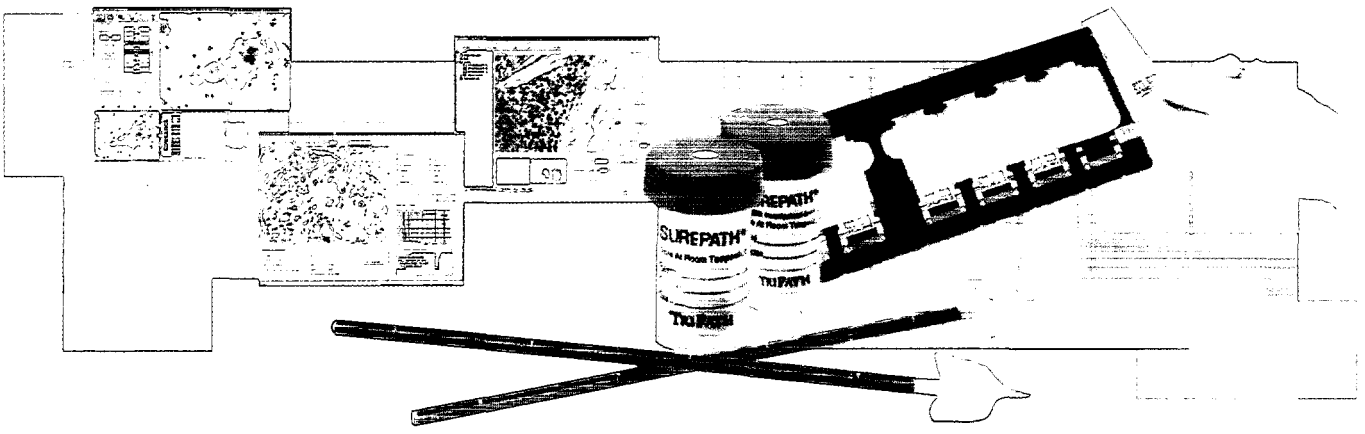
Looking Ahead

Given our progress in 2002, we are looking for 2003 to be another productive year...and why not?

We have defined a significant market opportunity. We have developed a unique and commercially tested bridging technology platform. We have an economically compelling business model. We are an established competitor in the cervical cancer screening market and we are well along in developing new

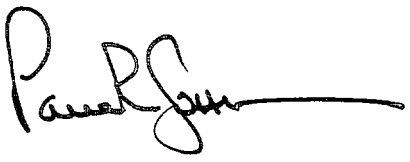
molecular diagnostic products and services. We have strong corporate relationships. We have cash, a manageable cash burn rate and a pathway to profitability and, most importantly, we are energized, focused, and committed.

For our commercial operations segment, our objectives are clear. We must continue to build sales, drive margin, generate cash, and create value for our customers. This will allow us to continue to build the infrastructure that will support an expanding product pipeline. While we will continue to focus on our core constituencies among academic centers of excellence, regional and hospital laboratories, and integrated provider networks, we also hope to accelerate our growth in the largest commercial labs in the U.S and further penetrate targeted markets outside the U.S.



The overriding objectives for TriPath Oncology in 2003 are also clear. First, to ready our analyte specific reagents for laboratory developed assays for staging of breast and cervical cancer for introduction in 2004 and second, to leverage the technology we have developed in support of our molecular diagnostic programs to enter into additional collaborations that will further expand our commercial opportunities.

We are increasingly optimistic about the opportunities ahead and we wish to thank our stockholders, our customers, and our employees for their continued support. Together we accomplished a great deal in 2002 and we are committed to positioning TriPath Imaging for success in 2003 and beyond.



Paul R. Sohmer, M.D.

President, Chief Executive Officer and Chairman of the Board

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

[X] 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: 0-22885

TRIPATH IMAGING, INC.

(exact name of registrant as specified in its charter)

Delaware	**56-1995728**
(State or other jurisdiction of Identification Number)	(I.R.S. Employer incorporation or organization)

780 Plantation Drive, Burlington, North Carolina 27215
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (336) 222-9707

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

None

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

Common Stock, $0.01 Par Value
(Title of each class)

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

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 28, 2002 was: $98,992,264.

There were 37,537,940 shares of the registrant's Common Stock outstanding as of March 19, 2003.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement of the Registrant for the Registrant's 2003 Annual Meeting of Shareholders to be held on May 22, 2003, which definitive proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year of December 31, 2002, are incorporated by reference into Part III of this Form 10-K.

TriPath Imaging, Inc.

Table of Contents

As used in this report, the terms "we," "us," "our," "TriPath Imaging" and the "Company" mean TriPath Imaging, Inc. and its subsidiaries, unless the context indicates another meaning.

Note Regarding Trademarks

PART I

Item 1. Business

This Annual Report on Form 10-K contains forward-looking statements, including statements regarding our results of operations, research and development programs, clinical trials and collaborations. Statements that are not historical facts are based on our management's current expectations, beliefs, assumptions, estimates, forecasts and projections. These forward-looking statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that could cause actual results to differ significantly from those discussed in these forward-looking statements. Important factors that could cause or contribute to these differences include those described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies" and in "Factors Affecting Future Operating Results" attached hereto as Exhibit 99.1 and incorporated by reference into this Form 10-K. You should not place undue reliance on the forward-looking statements, which speak only as the date of this report. We undertake no obligation to update these statements to reflect events or circumstances occurring after the date of this report or to reflect the occurrence of unanticipated events, except as required by law.

The Company's Internet website is *www.tripathimaging.com*. Information on the Company's website is not a part of this Form 10-K. The Company makes available free of charge on its website, or provides a link to, all of the Company's Forms 10-K, 10-Q and 8-K, and any amendments to these, that are filed with the SEC. To access these filings, go to the Company's website and click on "Investor Resources," then click on "SEC Filings."

The Company

We create solutions that redefine the early detection and clinical management of cancer. Specifically, we develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We were incorporated in October 1996 as AutoCyte, Inc. and changed our name to TriPath Imaging, Inc. in September 1999 in connection with the merger of AutoCyte, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed and marketed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We have created new opportunities and applications for our proprietary technology by applying recent advances in genomics, biology, and informatics to develop new molecular diagnostic and pharmacogenomic products and services for malignant melanoma and cancers of the cervix, breast, ovary, and colon.

We are organized into two operating units:

- Commercial Operations, through which we manage the market introduction, sales, service, manufacturing and ongoing development of our products; and

- TriPath Oncology, our wholly-owned subsidiary, through which we manage the development of molecular diagnostic and pharmacogenomic products and services for cancer.

We provide financial information by segment and geographic area in Note 8 to our Consolidated Financial Statements. We are incorporating that information into this section by reference.

Commercial Operations

During 2002, we adopted the trademark "TriPath Care Technologies" to describe our commercial product offerings and to communicate the broad nature of our corporate vision and the value created by our growing product portfolio, including the "i^3 Series" and SlideWizard product lines.

To further refine our market positioning and to enhance brand awareness among our customers, we have re-branded our cervical cancer screening products under the "i^3 Series" product line. Our "i^3 Series" product line for cervical cancer screening is the first integrated system for the collection, preparation, staining and computerized analysis of conventional Pap smears and liquid-based, thin-layer slide preparations. Our "i^3 Series " product line includes the following:

- *SurePath Test Pack* is a proprietary, liquid-based cytology sample collection, preservation and transport system. The SurePath Test Pack addresses errors in cell sample collection and slide preparation while providing a liquid medium for performing additional laboratory tests. The SurePath Test Pack was approved by the United States Food and Drug Administration ("FDA") for slides prepared using the PrepStain Slide Processor in June 1999. In 2001, SurePath was approved by the FDA for manual slide processing in which the cell suspension is layered onto the slide and stained by a cytotechnician.

- *PrepStain Slide Processor* is an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells. The PrepStain Slide Processor reduces the complexity of interpretation by providing a homogeneous, more representative and standardized thin layer of stained cells and a liquid medium for adjunctive laboratory testing of specimens. The FDA approved PrepStain in June 1999. In early 2003, we introduced a minor modification to the PrepStain slide processor that enables the system to be used either for cell transfer, slide preparation and staining, or for the cell transfer and preparation of slides that may be further processed using a laboratory's free standing automated slide staining system. This minor modification should provide more flexibility and facilitate the integration of the PrepStain system into laboratories whose workflow is organized around a free standing automated slide staining system. The PrepMate system, an accessory to PrepStain, is designed to automate several steps in the preparation of SurePath thin-layer slides. PrepMate automatically mixes and removes the specimen from the SurePath preservative fluid vials, and layers the specimen onto the SurePath density reagent in a test tube for automated slide preparation and staining. The FDA approved the PrepMate accessory in May 2001.

- *FocalPoint SlideProfiler* is a computerized imaging system that uses proprietary technology to automatically screen SurePath or conventionally prepared Pap smear slides. The FocalPoint Slide Profiler can identify those slides that have the highest likelihood of abnormality. Formerly known as the AutoPap Primary Screening System, FocalPoint was approved by the FDA as the first and only automated device for primary screening of conventional Pap smear slides for cancer of the cervix and its precursors in May 1998. In October 2001, FocalPoint was approved by the FDA to screen SurePath thin-layer slides. FocalPoint with Location Guided Screening (FocalPoint GS), the next generation FocalPoint system, was introduced outside of the U.S. in the fourth quarter of 2000. FocalPoint GS integrates our proprietary Slide Wizard technology into the FocalPoint screening process and automates the microscopic analysis of cervical smears designated for further review by the FocalPoint slide profiler. In early 2003, we initiated a multi-center clinical trial to collect data to support a Pre-market Approval ("PMA") supplement application for the FocalPoint GS employing an investigation plan that is the subject of a binding agreement with the FDA.

Our SlideWizard product line includes the Image Titer, an FDA cleared method for automating the measurement of antinuclear antibody, research applications for DNA, immunohistochemical quantification, cellular analysis, and expression quantification, a system for the transmission and interpretation of tissue specimens via remote telecommunications, or "telepathology," and a software based storage and retrieval system for microscopic images.

TriPath Oncology

Our TriPath Oncology business focuses on developing and commercializing molecular diagnostic and pharmacogenomic tests for a variety of cancers. On July 31, 2001, we entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize molecular diagnostics and pharmacogenomic tests for malignant melanoma and cancers of the cervix, breast, ovary, colon and prostate as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium").

Historically, the cancer diagnostics market has relied on tests or methods that identify surrogate markers or cellular abnormalities that are correlated with the presence or stage of disease, but provide limited information specific to the disease or patient outcome. In recent years, however, significant advances have occurred in the analysis and characterization of cancer from a molecular mechanistic perspective. Information derived from the analysis of gene and protein expression differences is providing new insights into the biology of cancer and is driving the discovery of novel molecular markers which correlate to the presence and stage of cancer and to patient outcome. The goal of our molecular oncology program is to utilize these new discoveries in genomics and proteomics research to develop and commercialize diagnostic and pharmacogenomic tests to improve the early detection and clinical management of cancer. Specifically, we have active programs in development designed to identify individuals with cancer at the earliest possible stage of the disease, provide individualized predictive and prognostic information, guide treatment selection for patients with cancer, and predict disease recurrence. The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified through discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology will clinically validate and develop these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. Commercial responsibilities for any resulting products will be shared between BD and TriPath Oncology. BD will continue to fund additional discovery research activities at Millennium at least through the end of their agreement in early 2004.

The key components of our product development strategy are as follows:

1. Identify and validate novel molecular marker panels based upon predetermined clinical specifications. The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified through discovery research, conducted at Millennium, under its existing research and development agreement with BD. Utilizing its proprietary technology and know-how in genomics and bioinformatics, Millennium has correlated the presence of specific genetic sequences (i.e., molecular markers) with a series of clinical specifications for each of our targeted cancers. These clinical specifications are based upon current unmet clinical needs and what we perceive to be a significant commercial opportunity. Since it is generally accepted that cancer onset and progression are driven by multiple inter-related genetic changes, our molecular assays will consist of panels of molecular markers which will yield molecular profiles, known as signatures descriptive of clinical phenotype and patient outcome.

2. Format our molecular assay technology into universally accepted laboratory assays. Our goal is to change clinical practice, not laboratory practice. Therefore, all of our assay technologies will be developed in commercially accepted formats to facilitate rapid laboratory adoption. The technology format selection is dependent upon sample type. For early detection assays, we have chosen an immunoassay format that is capable of detecting and quantifying multiple secreted proteins in blood. Staging and prognostic assays will require the quantification of molecular markers (proteins) within the context of cellular morphology, and as such, these assays will be formatted in a standard immunohistochemistry ("IHC") assay with colorimetric bright-field detection. Both formats are based on the detection and quantification of specific proteins and will thus require us to generate monoclonal antibodies targeted to each unique protein. We do this by first translating the unique gene sequences identified by Millennium into proteins using a number of protein expression systems, then developing monoclonal antibodies specific to each protein through standard hybridoma technology. After each monoclonal antibody marker is independently validated using clinical samples with known patient outcome, a marker panel will be assembled to achieve the desired assay sensitivity and specificity.

3. Link the staging and prognostic assays to our proprietary image analysis technology. We believe that in many cases clinical outcomes are determined by subtle differences in gene or protein expression, and that these subtle differences in gene and protein levels will require advanced imaging capability for quantification and interpretation. Furthermore, we believe that tissue architecture, cell morphology, and precise sub-cellular localization of molecular markers will be an important tool for accurate cancer staging and prognosis. Therefore, we intend to adapt our proprietary image analysis platform to our molecular assays to allow analysis and quantification of multiple, discrete molecular markers within the context of tissue distribution and cellular location.

We introduced our first analyte specific reagent ("ASR") which was used in a laboratory developed assay for malignant melanoma in the fourth quarter of 2002 through our collaborative agreement with AmeriPath, Inc., a leading national provider of cancer diagnostics, genomics and related information. In the third quarter of 2002, we completed marker discovery and initiated development work for molecular assays for cervical and breast cancer. We are actively translating unique gene expression patterns or markers provided by Millennium into proteins and monoclonal antibody reagents for adaptation into universally accepted commercial testing formats and have initiated pre-clinical validation studies. We anticipate introduction of ASRs for laboratory developed tissue and cell based assays for staging of cancer of the cervix and breast in late 2004.

We have completed development of a prototype version of our imaging platform to facilitate assay development. The proprietary imaging platform consists of four major components. The *Asset Tracking* component is used to register and track all clinical samples used in the development of our molecular assays, and to manage the slide images and data created from the samples. The *Automated Slide Scanner* component provides high throughput slide handling and scanning capability, and produces high-resolution digital images of cells and tissue stained with our molecular markers. These images can then be evaluated interactively by cytotechnologists and pathologists via the *Viewer* component of the platform. The *Quantification* component uses innovative, proprietary algorithms to analyze the digital slides, providing quantitative measurements for each different molecular marker on the slide. While the primary utility of this imaging platform today is to support our product development activities, we have already begun the process of adapting this technology to a commercial product which will ultimately be linked to our molecular assays.

We are also leveraging our proprietary imaging technology to develop new collaborations to expand our commercial opportunities. In early 2003, we entered into an agreement with Bristol-Myers Squibb Company ("BMS") to provide quantitative tissue based image analysis in support of their oncology therapeutics programs targeted at treating epithelial cancers, including cancer of the cervix, breast and colon. We are utilizing our SlideWizard image analysis platform and proprietary software applications to provide a quantitative assessment of tumor marker expression levels from tissue samples provided by BMS for patients enrolled in a Phase I clinical trial. The data generated by our work will be used to evaluate patient response across varied dosing levels based on changes in tumor marker expression levels, both before and after treatment.

We believe that our proprietary assets and technologies in imaging analysis, our broad access to novel molecular markers offered by our relationship with BD and Millennium, and our in-house expertise and capability in rare reagent and assay development will provide us with the necessary technology and expertise to successfully develop improved diagnostic oncology products. We further believe that the management of TriPath Oncology as a separate business unit provides a focused organization and dedicated management team with top-notch skills and expertise in assay formatting and development to deliver new oncology products to our commercial team which will dramatically improve the early detection and clinical management of cancer.

The Cancer Market

Cancer is a chronic and complex disease characterized by uncontrolled growth and spread of abnormal cells. According to the World Health Organization ("WHO"), the worldwide incidence of cancer in the year 2000 exceeded 10 million cases, excluding basal and squamous cell cancers of the skin. The WHO further estimates that approximately 6.2 million deaths worldwide were attributable to cancer in 2000. In the United

States, the American Cancer Society ("ACS") estimates that roughly 1.3 million cases of non-skin cancers were diagnosed in 2002, roughly half of which occurred in women. In the United States, women have about a 1-in-3 lifetime risk of developing invasive cancer. It is estimated that in 2003 approximately 658,800 women will be newly diagnosed with cancer and an estimated 270,600 women will succumb to the disease. It is anticipated that melanoma and cancers of the breast, cervix, ovary, colon and rectum will account for over one half of all cancers diagnosed in women in 2003.

Women's Cancers
2003 Cancer Estimates (U.S.)

	Estimated 2003 Incidence	Estimated 2003 Mortality
All Cancers	658,800	270,600
TriPath Imaging Targeted Cancers:		
Breast	211,300	39,800
Colorectal	74,700	28,800
Ovarian	25,400	14,300
Malignant Melanoma	24,300	2,900
Cervical	12,200	4,100

Source: American Cancer Society

Treatments for cancer are expensive and oftentimes ineffective. Current treatments for cancer include surgery, radiation, and chemotherapy. Surgery is limited in its effectiveness because it treats the tumor at a specific site and may not remove all the cancer cells, particularly if the cancer has spread. Radiation and chemotherapy can treat the cancer at multiple sites but can cause serious adverse side effects because they destroy healthy cells and tissues as well as cancer cells. The ACS projected that in 2002 over 250,000 women died of cancer-related illness. Detecting cancer at the earliest possible stage of disease is critical to patient survival and outcome as reflected in the following five-year relative survival rates:

Five Year Disease-Free Survival
by Stage at Diagnosis

TriPath Imaging Targeted Cancers:	Local (%)	Regional (%)	Distant (%)
Breast	97	78	23
Colorectal	90	65	9
Ovarian	95	81	31
Malignant Melanoma	96	60	14
Cervical	92	51	15

Source: American Cancer Society

Development and utilization of modalities for routine cancer screening is critical to early detection. According to the ACS, whereas the five-year relative survival rate for all cancers is approximately 62%, the relative survival rate for currently screened cancers (i.e. including cancers of the cervix, breast, colon, rectum and skin) is approximately 82%. ACS estimates that the relative survival rates of these screened cancers could be further increased to 95% if all Americans were regularly screened for these cancers. In 2002, the National Institutes of Health ("NIH") estimated the overall costs for cancer-related illness in the U.S. to be $171.6 billion.

The market for cancer diagnostics is expected to grow substantially due to the increased incidence of cancer, an aging population, early cancer awareness, pressure to reduce cancer mortality rates and improvements in healthcare screening systems. The existing cancer diagnostics market is characterized predominantly

by tests or methods that identify the presence of surrogate markers of disease, cellular abnormalities or imaging anomalies that are correlated with the presence or stage of disease but, for the most part, do little to provide information specific to the biology of the disease or the outcome of the patient. The current technologies used in cancer diagnostics consist primarily of tumor marker immunoassays, cytology evaluation and imaging techniques such as mammography.

While some of the underlying causes of specific cancers can be traced to a single genetic alteration, it is now believed that multiple complex genetic changes underlie the development of the vast majority of cancers. However, the identification of genetic anomalies alone is unlikely to prove clinically significant as many genetic events may have minimal or no impact on a patient's health, whereas others may pose life-threatening health risks. Determining the interrelationship of genes and proteins, and their interaction with one another will be as important as understanding the underlying cause of the genetic change itself. The scientific community's knowledge of these underlying genetic factors has only recently come about through the development of more sophisticated research and discovery tools, investment in mapping of the human genome, and development of bioinformatics capabilities to assess the clinical relevance of these genetic abnormalities.

In recent years, novel molecular oncology tests have been introduced to provide additional clinical information previously unavailable to assess an individual's predisposition or lifetime risk of developing certain cancers. Molecular tests are also used to screen and assist in the diagnosis of the presence of disease, to assess patient prognosis and outcome more accurately, to guide therapeutic selection in the management of certain cancers and to monitor for disease recurrence. Molecular tests offer the promise of providing a more accurate, disease-specific understanding of cancer to best address the needs of medical practitioners.

Cervical Cancer

Cancer of the uterine cervix, or cervical cancer, is second only to breast cancer as the most common form of malignancy in both incidence and mortality worldwide. According to World Health Organization ("WHO") the worldwide incidence of cervical cancer in 2000 were 470,606 with a mortality rate of 233,372. In parts of the developing world, cervical cancer is the major cause of death in women of reproductive age. The American Cancer Society estimates that in 2003 approximately 12,200 cases of invasive cervical cancer will be diagnosed in the United States with an estimated 4,100 deaths.

Invasive cervical cancer spreads from the surface of the cervix to tissue deeper in the cervix or to other parts of the body. Cervical cancer develops in stages over a period of time beginning with pre-invasive changes that eventually progress to invasion. Because of the progression to invasion, most deaths due to invasive cervical cancer can be prevented with early-stage detection and treatment. Early detection is critical in promoting patient wellness. The more advanced the cancer, the lower the chances are of managing and/or curing the patient. Thus, regular cervical screening examinations are recommended in the United States and many foreign countries.

The Conventional Pap Smear

The conventional Pap smear is currently the most widely used screening test for cervical cancer. This test was developed by Dr. George N. Papanicolaou in the 1940's and has essentially remained unchanged until the advent of liquid-based cytology and automated computer primary screening. The Pap smear detects pre-cancerous lesions before they invade the cervix while they are 100% curable. It is estimated that clinical laboratories in the United States perform over 50 million Pap smears annually. We believe that annual test volume outside of the United States is in excess of 80 million. Of the 50 million annual Pap smear tests performed in the United States, industry sources estimate that approximately 2.5 million, or five percent, are diagnosed at the pre-cancerous or cancerous stage.

In the United States, although widespread and regular use of the conventional Pap smear has contributed to a greater than 70% decrease in deaths resulting from cervical cancer, the death rate from the disease has declined at a rate of only approximately 1.6% per year. We believe that despite the success of the conventional Pap smear as a diagnostic tool, there are practical limitations to this test which contribute to in excess of $5.0 billion in annual costs. These costs are associated with the treatment of advanced pre-cancerous and

cancerous cervical disease. Additional costs are also incurred by third-party payers due to repeat testing for poor quality smears and by clinical laboratories due to litigation associated with inaccurate diagnoses. The introduction of liquid-based cytology has improved specimen adequacy and automated computer screening has improved diagnostic accuracy.

The evaluation of conventional Pap smears involves the science of cytology, which includes the microscopic evaluation and interpretation of pre-cancerous and malignant morphological changes in cells. The process begins with the collection of cervical cells during a gynecologic pelvic examination. To obtain a Pap smear, a clinician uses a sampling device to scrape the surface of a woman's uterine cervix to collect a sample of cervical cells. If the conventional Pap smear method is used, this sample is smeared onto a microscope slide and the sampling device is discarded. If our SurePath liquid-based method is used, the collection device itself is placed into a vial containing our transport and preservative solution and the cells are suspended in this liquid medium.

After the cervical sample is taken, the sample and patient information are sent to a clinical laboratory for further processing, screening and diagnosis. A cytotechnologist who is specially trained to evaluate cell changes screens and interprets the slide using a microscope. Any abnormality is further reviewed by a medical doctor or pathologist.

Typically, about 90% to 95% of all Pap smears are classified as normal. Pap smears classified as other than normal specify the degree of abnormal change. For example, atypical cells, commonly referred to as "atypia," represent the least significant change with a very low likelihood to progress to cancer if left untreated. They are generally classified as "ASCUS-US", which refers to atypical squamous cells of undetermined significance; or "ASC-H", which refers to atypical squamous cells-cannot exclude a high-grade lesion. The next classification is "LSIL", which is defined as low-grade squamous intraepithelial lesions, encompassing HPV/mild dysplasia/CIN 1 which has a slightly higher likelihood of progressing to cancer if left untreated but overall is still relatively low. "CIN" refers to cervical intraepithelial neoplasia, and is categorized as CIN 1, CIN 2, and CIN 3. "HSIL", defined as high-grade squamous intraepithelial lesions, encompassing moderate and severe dysplasia, CIN 2 and CIN 3, represents changes that biologically have the highest likelihood of progressing to cancer if left untreated. The most serious classification is the diagnosis of cancer itself. Optimally, the Pap test's objective is to detect the atypical to HSIL lesions as well as early invasive cancer so the lesion can be treated and the patient cured.

Limitations of the Conventional Pap Smear Test Process

Each Pap smear slide sample typically contains 50,000 to 300,000 cervical cells. The process of manually screening and interpreting a conventional Pap smear requires intense visual examination of the slide sample through a microscope. Because abnormal cells are not always visible, errors may occur and abnormal cells may not be seen by the cytotechnologist during the microscopic review process. Abnormal cells can be obscured by blood, mucus or white blood cells making them difficult to find and interpret. Other factors such as air-drying distorts the cells, resulting in normal cells being misinterpreted as abnormal, or abnormal cells being misinterpreted as normal. Most of these limitations are a result of poor specimen quality and have been shown to be minimized by using a liquid-based collection method.

Pap smears also have a highly variable false-negative rate. A false-negative results when the patient actually has evidence of disease but the Pap smear is reported as negative. False-negative rates of the conventional Pap smear vary widely among laboratories and have been reported to range from 2% to 28% according to studies at both Mercy Hospital in Janesville, Wisconsin and at Newport Hospital in Rhode Island. Factors that contribute to false-negative results vary but have been shown to depend on the skill and experience of the practitioner who collects the sample and prepares the slide. Studies actually suggest that the highest percentage of false-negative diagnoses are the result of inadequacies in sample collection and slide preparation. In this situation, the abnormal cells are either not collected properly on the sampling device or are collected properly on the sampling device but are not transferred properly to the microscopic glass slide. Other causes of false-negatives are attributable to detection and interpretation errors where abnormal cells are present on the Pap smear but they are either not seen at all, or are seen but interpreted as negative.

A study published in 1992 in the Acta Cytologica reported that, with a conventional Pap smear, as much as 80% of the sample taken from a patient may not be transferred to the slide and remains on the discarded collection device (Hutchinson M Patten FW, Stetzer GT, et.al.). In addition to inadequate cell transfer, the conventional Pap smear slide preparation process may produce inconsistent and non-uniform slides with extreme variability in quality, often making examination difficult. If a Pap smear is interpreted as unsatisfactory or less-than-optimal because of poor quality sampling or because of obscuring factors, the clinician may be prompted to call the patient back for a repeat test.

When using the conventional Pap smear process, a physician is unable to perform additional testing using the original patient sample. If additional testing is required, the patient must return to the physician's office to provide a second sample. This can cause a great deal of stress to the patient, thereby reducing the accuracy of the second sample. The SurePath liquid collection method allows the laboratory access to the remaining cellular material from the original patient sample. Repeat and ancillary testing from the residual cell solution may provide a more cost effective patient management program for inconclusive Pap smear tests, and may reduce a patient's stress and anxiety associated with repeat testing.

Due to the inherent limitations of the Pap smear screening process, a number of notable lawsuits were filed in the 1980s on behalf of women who died of cervical cancer and whose Pap smears, initially classified as normal, were subsequently determined to contain abnormal cells and, if classified differently, may have led to treatment that would have prevented death. These actions raised medicolegal concerns related to the inherent false-negative rate of Pap smears (reported in the range of 10%-45% by the Clinical Preventive Services, U.S.) resulting in a significant increase in the number of Pap smears categorized as either ASCUS, AGUS or LSIL. Consequently, the number of colposcopy procedures increased dramatically leading to increased health care costs as up to 80% of the procedures performed do not uncover underlying HSIL or cancer. To respond to address this need, tests for the detection of human papilloma virus have become increasingly utilized for women with ASCUS pap results.

Human Papilloma Virus

HPVs comprise a group of more than 70 types of viruses. Certain (non-cancerous) HPV types cause the common warts that grow on hands and feet and those that develop in the mouth and genital areas. Genital HPVs can be passed from one person to another through sexual intercourse and oral or anal sex. Certain genital HPV types, called "high risk" HPV types and include HPV-16, HPV-18, HPV-31, HPV-45, as well as some others, can cause the growth of abnormal cells in the cervix that could potentially lead to the development of invasive cervical cancer. In fact, it has been documented that nearly all cervical cancers (99.7%) are directly linked to previous infection with one or more of the oncogenic (cancer-inducing) types of HPV (Judson 1992; Walboomers et. al. 1999).

Whereas the vast majority of cervical disease can be traced to an underlying HPV infection, identification of infection, even with a high-risk type, is not in and of itself predictive. HPV is the most prevalent sexually transmitted infection in the world, occurring at some point in up to 75% of sexually active women (Groopman 1999). Although HPV infection is widespread, few people even know they are infected because they seldom have noticeable symptoms. While women usually are infected shortly after they become sexually active in their teens, 20s or 30s, progression to cervical cancer generally takes place over a period of 10 to 20 years. In rare instances, some early lesions can become cancerous over a shorter time interval such as a year or two.

It is estimated that for every 1 million women infected, about 10% will develop pre-cancerous changes in their cervical tissue (dysplasia). Of these, about 8% will develop early cancer limited to the outer layers of the cervical cells (carcinoma *in situ* or "CIS") and roughly 1,600 will develop invasive cancer unless the pre-cancerous lesions and CIS are detected and treated. Finally, women with active infection can transfer the virus to their newborn (vertical transmission) during delivery, which can result in papilloma virus infection in the neonate and possible subsequent laryngeal papillomatosis (Cason, Rice and Best 1998).

In most cases an active infection is controlled by the immune system and with time becomes dormant; however, it is not possible to predict whether or when the virus will become active again. For example, one recent study followed more than 600 female university students who were tested every 6 months (Groopman

1999). Over the course of 3 years, new HPV infections occurred in more than 40% of the women. Most infections lasted about 8 months and then subsided. After 2 years, however, about 10% of the women still carried active virus in the vagina and cervix. In this study, the persistent infections were most commonly with the virulent, cancer-linked types of viruses.

Limitations of HPV Testing

Over the past three years, HPV testing has gained clinical acceptance in the U.S. for supplemental testing of women for whom the results of primary cervical cytologic screening are atypical (ASCUS-US) but of uncertain significance and not clearly diagnostic of pre-malignant or malignant disease. Supplemental testing with HPV provides guidance as to how these patients should be managed. A negative HPV test is highly predictive of the absence of pre-malignant or malignant cervical disease and, therefore, is said to warrant no further action. A positive HPV test is said to warrant further examination including colposcopy. HPV infection rates in young women, i.e. less than 30 years of age, have been shown to be as high as 80% in certain populations thereby limiting the utility of the test for women of all ages. In addition, the high positive rate in women with a cytology diagnosis of LSIL limits the value of the test in this subset of patients, as well.

Attempts have been made to promote HPV testing without concurrent examination of cervical cytology as a primary screening tool for cervical cancer in some countries outside the U.S. where the infrastructure to interpret cervical cytology slides is lacking. This approach is unlikely to be utilized in the U.S. and other markets where cytology screening capability exists, particularly given the high prevalence of HPV in women less than 30 years of age.

In the U.S., the FDA is currently reviewing a submission by Digene® Corporation, the manufacturer of the only currently FDA approved test for HPV, called the Digene Hybrid Capture® HPV Test, for expanded claims to include an indication to use HPV testing in conjunction with cervical cytology for primary screening for cervical cancer in women over the age of 30. Recent prospective trials conducted by the National Cancer Institute suggest that routine screening of HPV DNA combined with cytology would result in the greatest detection of cervical dysplasia. However, while a negative HPV test result is highly predictive of the absence of pre-malignant or malignant cervical disease, the predictive value of a positive HPV test result may be limited because HPV testing cannot distinguish non-progressive infection from infections that would benefit from therapy.

Breast Cancer

With an estimated incidence of over one million new cases per year, cancer of the breast is the most common women's cancer in the world accounting for 22% of all new cases diagnosed. On a worldwide basis, breast cancer is the leading cause of cancer mortality in women representing an estimated 14% of all cancer-related deaths in females.

The American Cancer Society estimates that in 2003, approximately 211,300 new cases of invasive breast cancer will be diagnosed among women in the United States, with an estimated 40,200 women dying of the disease. Breast cancer incidence increases with age, and although significant progress has been made in identifying women considered to be at high risk of developing the disease, more than 50% of breast cancer occurs sporadically in women with no known risk factors. According to the National Cancer Institute ("NCI"), the overall five-year survival rate for women diagnosed with breast cancer is 86%. Early detection is paramount as the relative survival rates vary significantly among localized disease (96.8%), regional spread (78.4%) and distant metastases (22.5%).

Breast Cancer Screening

Breast cancer screening is currently defined as a combination of patient self-exam, clinical breast exam and mammography. These methods are complementary and are not used as stand-alone techniques. Film imaging mammography is the gold standard for breast cancer screening and currently represents the most effective means of early detection of breast cancer with a sensitivity ranging from 54.0% to 94.0% and a specificity ranging from 83.0% to 98.5%. More specifically, studies show that mammography sensitivity ranges

from 54.0% to 58.0% in women under age 40 and from 81.0% to 94.0% in women over 65. The primary purpose of mammography screening is the detection of an abnormality. Numerous studies have shown that early detection saves lives and provides more treatment options. For this reason, annual screening by mammography is recommended for women over age 40 in the U.S. and many foreign countries.

According to data from the 2000 Behavioral Risk Factor Surveillance System ("BRFSS"), the percentage of U.S. women aged 40 and older who had a recent mammogram was 62.6%. Of the 32.5 million screening mammograms currently performed in the U.S., approximately 4 million indicate some form of abnormality requiring further follow-up. Once an abnormality is detected on initial screening, the need for a very sensitive and specific assay to detect early breast cancer becomes critical. Although follow-up diagnostic imaging and ultrasound may provide greater image clarity, neither is able to distinguish between a benign condition and a malignancy. Of the estimated 1.2 million breast biopsies performed in the U.S., roughly 80% yield no form of malignancy resulting in an estimated cost of $3.3 billion related to unnecessary biopsies.

Breast Cancer Staging and Treatment

Once breast cancer is diagnosed, it is staged, (i.e. I, II, III or IV) based on a number of factors including tumor pathology ("T"), nodal involvement ("N") and distant metastasis ("M"). In the U. S., approximately 55% to 60% of newly diagnosed invasive breast cancer is detected at a relatively early stage (i.e. small tumor size and with no or minimal nodal involvement).

Although the "TNM" classification system is useful in staging patients for follow up and treatment, it is based solely on the morphologic features of the tumor and its degree of spread and, thus does not take into consideration the biologic make up of the cancer. The clinical course of primary breast cancer varies from patient to patient. Predicting which individuals are cured and which are not remains difficult for both lymph node negative and lymph node positive breast cancer patients. Clinicians are well aware that some patients who have poor TNM scores have long disease-free survival times, whereas others with good TNM scores experience a rapid deterioration with early recurrence of breast cancer followed by death. At best, current prognostic indicators serve as guides for clinical decisions that require considerable judgment.

Once the cancer is staged, treatment decisions are typically made by an oncologist in consultation with the patient and will take into consideration the patient's age and preferences, as well as the risks and benefits associated with each treatment protocol. Nearly all women with breast cancer will have some form of surgery combined with other treatments such as radiotherapy, chemotherapy, hormone therapy and/or monoclonal antibody therapy. Prognostic tests for the determination of estrogen receptor ("ER"), progesterone receptor ("PR") and her2/neu status have become standard of care for selecting subsets of patients most likely to benefit from certain hormone and monoclonal antibody therapies.

Post-Therapy Recurrence

In general, it has been widely assumed that early detection of any cancer, whether as a new primary malignancy or as a recurrence, leads to more effective therapy. As with screening, the ability to detect small tumors and early progression in asymptomatic situations is paramount to positive outcomes. However, the recurrence rate can be as high as 25% to 30% within the first five years after diagnosis, even in patients with good TNM scores.

Presently, a large number of markers exist for the monitoring of breast cancer. These include MUC-1 (CA15-3), carcinoembryonic antigen ("CEA"), oncoproteins, milk proteins and cytokeratins. Of these, CA15-3, CA27.29 and CEA are the most commonly used. According to the American Society of Clinical Oncologists, ("ASCO") Tumor Marker Guidelines, the performance of these markers range in sensitivity for Stage I disease of 9% to 10%, Stage II of 19% to 54%, Stage III of 31% to 54% and Stage IV of 64% to 75%. Additionally, ASCO notes that CA15-3 exhibits a limited sensitivity for detecting low tumor burden, when treatments are most likely to be beneficial. Currently, only 20% to 30% of recurrences are detected before the onset of symptoms.

Ovarian Cancer

Ovarian cancer is only the seventh most common cancer in women with an estimated 192,379 cases diagnosed worldwide in 2000, but it is among the most deadly. In the U.S., the five-year relative survival rate is only 53% for all women diagnosed with ovarian cancer. According to the NCI, the five year relative survival rate for localized ovarian cancer is 94.9%, but only 81.4% if the cancer has spread regionally, and only 30.9% for women with distant metastases.

Ovarian cancer has been shown to be a clonal disease in approximately 90% of cases suggesting that most cancers could, in fact, be detected before they have metastasized. Due to the lack of an adequate screening test, and to the fact ovarian cancer is asymptomatic until the cancer has progressed to a late stage, approximately 75% of newly diagnosed patients are in advanced to late stages III and IV.

Ovarian Cancer Screening

The effectiveness of routine screening of asymptomatic women using pelvic examination, abdominal or vaginal ultrasound or serum carcinoembryonic antigen (CEA-125) has not been established. The ACS recommends annual pelvic examinations for women starting at age 18 or at the onset of sexual activity. In 1994, a National Institutes of Health Consensus Conference on Ovarian Cancer concluded that there is no evidence that screening with current available modalities, including CEA-125 and/or transvaginal ultrasound can be used effectively to decrease ovarian cancer mortality or morbidity.

Currently, screening for ovarian cancer typically occurs in one of the following settings:

- *Women considered at high risk for developing ovarian cancer.*
  The ACS states that women who are at high risk of epithelial ovarian cancer, such as those with a very strong family history of the disease, may be screened annually using transvaginal ultrasound and/or CEA-125.

- *Presence of adnexal (ovarian) or pelvic mass.*
  In the United States the hospitalization rate for ovarian neoplasms is reported to be as high as 289,000 women annually. Roughly 80% to 90% of these women will have a surgical procedure to rule out and/or diagnose ovarian cancer. An even greater number of women are found to have an adnexal or pelvic mass during a routine physical examination or during evaluation for another complaint.

A successful screening program aimed at the early detection of ovarian cancer would require that major abdominal surgery (laparoscopy and/or laparotomy) be performed, as this is the only means of a definitive diagnosis. Because of the low incidence of ovarian cancer and the necessity of major abdominal surgery, a screening program requires high accuracy with a high specificity to minimize morbidity associated with major abdominal surgery.

Colorectal Cancer

In 2000, there were an estimated 445,963 cancers of the colon and/or rectum diagnosed in women, making it the third most common female malignancy worldwide according to the WHO. Colorectal cancer also ranks as one of the more deadly cancers attributable to over 237,000 cancer-related deaths in women worldwide. In the U.S., the ACS estimates that almost 75,000 women will be diagnosed with colorectal cancer in 2003, and an estimated 28,000 will die of the disease this year.

Similar to most cancers, survival rates for colorectal cancers can be very high if detected at an early stage (i.e. the five-year relative survival rate for localized disease is 90%). Unfortunately, only 37% of colorectal cancers are detected before the cancer has spread. Once the cancer has spread to the regional nodes, the relative survival rate is only 65% and for distant metastases, the survival rate drops to 9%.

Colorectal Cancer Screening

The primary risk factor for developing colorectal cancer is increasing age with more than 90% of cases diagnosed in individuals over the age of 50. Screening can prevent the occurrence of colorectal cancer by

detecting and removing pre-cancerous polyps or it can diagnose early disease at a stage when it can be effectively cured. The ACS guidelines recommend screening individuals starting at age 50 by one of the following five screening strategies:

- Yearly fecal occult blood test plus flexible sigmoidoscopy every five years
- Flexible sigmoidoscopy every five years
- Yearly fecal occult blood test
- Colonoscopy every ten years
- Double contrast barium enema every five years

Although the fecal occult blood test is the least invasive method and most amenable to widespread screening, it has significant drawbacks including low sensitivity (ranges from 35% to 40% for detecting of colorectal cancer) and poor patient compliance.

Malignant Melanoma

Although melanoma accounts for only a fraction of all skin cancers diagnosed, it is by far the most serious. Unlike the more common and curable basal cell and squamous cell skin cancers, melanoma accounts for roughly 75% of all skin cancer-related deaths. In 2000, the WHO estimated that 67,425 cases of melanoma were diagnosed in women and 17,045 female deaths were attributable to this deadly disease. In 2003, in the U.S., an estimated 24,300 women will be diagnosed with melanoma and 3,600 are expected to die of the disease.

The overall five year relative survival rate of patients diagnosed with melanoma is 89% according to the ACS. Because melanoma develops from biological changes in pigmented lesions such as moles, early signs of melanoma development can usually be seen through changes in the size, color or texture of the lesion. As a result, about 82% of melanomas are diagnosed at an early or localized stage where the five-year relative survival rate approximates 96%. Survival rates drop considerably to 60% and 14% for melanomas that have spread to regional nodes or to distant organs, respectively.

Melanoma Staging and Treatment

Once melanoma is suspected, the lesion and surrounding tissue are excised. Once diagnosed, biopsy of the surrounding (sentinel) lymph nodes is common to determine the degree of spread of disease. Like most cancers, melanomas are staged, i.e. I, II, III or IV, based on a number of factors including tumor pathology ("T"), nodal involvement ("N") and distant metastasis ("M"). Prognostic factors such as tumor thickness (Clark Score), mitoses and ulceration are among the criteria used in tumor grading. Although the TNM classification system is useful in staging patients for follow up and treatment, it is based solely on the morphologic features of the tumor and its degree of spread and, thus does not take into consideration the biologic make up of the cancer.

Predicting which individuals are cured and which are not remains difficult, as up to 20% of individuals with thin lesions may relapse within 5 years. Clinicians are well aware that some patients who have poor TNM scores have long disease-free survival times, whereas others with good TNM scores experience a rapid deterioration with early recurrence of melanoma followed by death. At best, current prognostic indicators serve as guides for clinical decisions that require considerable judgement.

In addition to the standard treatment for malignant melanoma, which includes adequate excision of the primary tumor and may require removal of surrounding lymph nodes, advanced cases are treated with chemotherapy or immunotherapy. Although a number of markers have been studied to determine their utility in predicting which patients with early stage disease have biologically aggressive disease and, therefore should be treated more aggressively, determination of melastatin mRNA expression levels appears to be the most promising.

Our Products

The i^3 Series Product Line

Our i^3 Series product line of cervical cytology products is intended to address the current limitations of the conventional Pap smear process and the lack of automation in the cytopathology laboratory. The products within our i^3 Series product line work together as part of an integrated system for the collection, preparation, staining and computerized analysis of liquid-based, thin-layer Pap preparations and the screening of conventional Pap smears. The silent exponent "3" suggests the expertise contributed by each of our three predecessor companies, AutoCyte, NeoPath and NSI, as well as the value of these component products in providing intelligent identification through innovation. Within the i^3 Series line, individual products have been renamed to better communicate the value they provide to the physician, patients and laboratory professionals. Our i^3 Series line of cervical cytology products includes the SurePath Test Pack, a proprietary, liquid-based cytology sample collection, cell preservation and transport system, the PrepStain slide processor, an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells, and the FocalPoint Slide Profiler which utilizes proprietary technology to distinguish normal liquid-based or conventional Pap smears from smears that have the highest likelihood of abnormality.

The SurePath Test Pack

Our SurePath Test Pack consists of a sample collection vial, proprietary preservative solution and sample collection device. During a clinical exam, a physician or nurse will collect a sample of endocervical and ectocervical cells, currently using a cervical broom collection device. Once collected, the health practitioner detaches the removable head of the collection device and places it into the vial containing our proprietary SurePath preservative fluid, thereby retaining 100% of the cells collected. The lid of the vial is then fastened and the vial is then transported to the clinical laboratory for follow-on processing on the PrepStain system.

Although SurePath has been FDA-approved for use with a cervical broom collection device, we initiated clinical trials in the third quarter of 2002 to evaluate the safety and efficacy of alternate sample collection devices, including the cervical spatula and cervical brush. We hope to receive FDA approval for clinical use of these alternative collection devices in the second half of 2003. There can be no assurance, however, that such approval will be obtained during the second half of 2003, or ever, nor that if approved, there will be widespread market acceptance of the alternate devices contemplated by our clinical studies.

In July 2002, Digene Corporation ("Digene") informed us that it had received a "not approvable" letter from the FDA for its Pre-Market Approval Supplement application to use SurePath as a specimen collection medium for its Hybrid Capture® 2(hc2) HPV DNA Test. We are working with Digene and the FDA to resolve the issues identified in the letter. Although we will be collecting and submitting clinical additional data to the FDA, we remain hopeful that resolution of the issues identified by the FDA will not alter our expectations for approval in late 2003. There can be no assurance, however, that we will succeed in resolving the issues raised by the FDA, nor in gaining approval for the combined use of our products from the FDA.

The PrepStain System

Our PrepStain system consists of proprietary reagents, plastic disposables and automated equipment for preparing a thin-layer of cervical cells on a SurePath microscope slide. Once received in the laboratory, the sample is thoroughly mixed, resulting in a randomized cell suspension which is removed from the vial and layered onto a proprietary liquid density reagent in a plastic centrifuge tube using our patented syringe device. Batch centrifugation is then conducted on the cell suspension to remove excess blood, inflammatory cells and other debris from the sample.

Once centrifugation is completed, the laboratory technician places the tube containing the separated diagnostic cells onto an automated pipetting system. This pipetting system then distributes the cervical cells in a thin-layer on the microscope slide. At this stage, discrete staining of the slides can be carried out by the PrepStain system, or staining can be performed off-line from the PrepStain using alternative staining instrumentation. PrepStain is currently capable of preparing approximately 48 discretely stained or 96

unstained thin-layer slides in approximately one hour. A SurePath slide typically contains approximately 50,000 to 100,000 diagnostic cells that are distributed uniformly over a 13-mm diameter circle.

We have also developed an automated accessory to the PrepStain system called PrepMate that reduces the number of manual preparation steps required on the PrepStain system. The PrepMate accessory is intended to reduce the time required to prepare samples for processing on the PrepStain instrument. The FDA approved PrepMate for use in the U.S. in May 2001.

We believe that SurePath and PrepStain offer the following advantages over the conventional Pap smear process:

- *More Complete Sample Collection.* Because the clinician places the collection device directly into the SurePath vial, the entire patient sample is contained in our preservative fluid. In a conventional Pap smear process, as much as 80% of the cervical sample can be inadvertently discarded with the disposable collection device after smearing the sample onto the slide.
- *Improved Sample Quality.* By eliminating variations in preparation techniques and the fixative spraying step from the sample collection process, PrepStain virtually eliminates air-drying, generates a more complete fixation, and provides a more standardized preparation process in a controlled, laboratory environment. This more uniform cell sample distribution also reduces cell clumping and obscuring from debris.
- *Automated and Discrete Staining Function.* PrepStain includes a discrete, or individualized, slide staining function performed by a computer-controlled robotic pipetting station. Unlike conventional Pap smear slides that are often manually stained in a batch process using common reservoirs of staining reagents, PrepStain's staining reagents are directly applied to individual slides. As a result, staining reagents are not shared among slides. We believe this reduces the risk of cross-contamination among cell samples that can lead to inaccurate diagnoses.
- *Staining Flexibility.* In early 2003, we introduced a minor modification to the PrepStain system that allows the system to be used for cell transfer, slide preparation and staining or for the cell transfer and preparation of slides that may be further processed using a laboratory's existing free-standing automated slide staining system. This provides flexibility and facilitates the integration of the system into laboratories whose workflow is organized around a free-standing automated staining system.
- *Multiple Testing Capability.* Because our proprietary SurePath preservative system enables the patient sample to be preserved for four weeks at room temperature and six months if refrigerated, it permits, if necessary, preparation of several slides from a single sample. We believe that the ability to perform adjunctive slide-based tests using a single sample, together with the improved quality of the slide itself, will reduce re-testing expenses typically associated with inconclusive Pap smear tests. We will evaluate use of the residual patient sample for other diagnostic protocols such as HPV testing, infectious disease testing and application of specific tumor markers. Residual sample testing will require FDA approval if and when such testing is determined to be viable.

FocalPoint Slide Profiler (formerly AutoPap Primary Screening System)

The FocalPoint Slide Profiler is an automated, computerized primary interpretation system designed to distinguish between normal and abnormal Pap smears. FocalPoint was approved by the FDA in May 1998 as a primary screening device for conventional Pap smear slides. In October 2001, the FDA approved the use of FocalPoint as a primary screening device for our SurePath thin-layer slides prepared by PrepStain. FocalPoint uses visual intelligence algorithms to improve accuracy in the primary screening of conventional Pap smear slides and our SurePath thin-layer slides. As approved by the FDA, FocalPoint identifies up to 25% of slides as "within normal limits" and requiring no further review (also referred to as "sort rate" or "no further review rate"). Cytotechnologists then manually screen the remaining slides with the assistance of FocalPoint's ranked review report. This ranked review report shows the relative scores of the remaining processed slides. At least 15% of the highest-ranking slides that are classified normal by manual review then undergo quality control re-

screening. Outside the United States, FocalPoint is used, in some instances, to identify up to 50% of slides as "within normal limits."

FocalPoint works with a range of staining procedures used on conventionally-prepared Pap smear slides. FocalPoint analyzes a Pap smear in about five to six minutes, holds 288 Pap smear slides at once, is easy to load and unload and can operate continuously with minimal intervention for up to 24 hours per day. We provide each clinical laboratory with on-site training, system documentation, a comprehensive quality assurance program and ongoing customer and technical support.

FocalPoint GS

In the fourth quarter of 2000, we launched FocalPoint GS, the next generation FocalPoint system for use outside the United States. FocalPoint GS uses Location Guided Screening to further improve the screening process by automating the microscopic analysis of SurePath thin-layer slides or conventional Pap smears designated for further review by the FocalPoint Slide Profiler. FocalPoint GS integrates our SlideWizard technology into the FocalPoint screening process. The FocalPoint instrument is interfaced to our SlideWizard platform and networked to one or more commercially available microscopes that have been equipped with computer-controlled automated stages for fast relocation of "fields of interest" on microscopic slides. During the initial screening process, and for each slide screened, FocalPoint GS identifies and stores a pre-set number of "fields of interest" in which it has calculated a higher probability of abnormality. As with the FocalPoint Slide Profiler screening process, FocalPoint GS identifies up to 25% of slides as "within normal limits" for which no further review is required. For each of the remaining slides, FocalPoint GS communicates the location coordinates of the "fields of interest" to the computer controlled microscope stage via the SlideWizard platform. The "fields of interest" are electronically highlighted and located for easy identification. This facilitates a focused microscopic review and allows the cytotechnologist to quickly analyze the slide for the presence of cellular abnormality. Abnormal findings thus identified can be confirmed by full microscopic review. If no abnormality is identified during this rapid cytologic assessment, no further review is required.

We believe the established quality of the FocalPoint algorithms, coupled with the highly focused nature of location-guided screening, allow laboratories to improve quality, increase capacity by up to 200% and alleviate backlogs and/or labor shortages. To date, the FocalPoint GS has been used to screen over 2 million slides outside of the U.S.

In early 2003, we initiated U.S. clinical trials under a binding protocol with the FDA, to obtain data to support an application for U.S. approval of FocalPoint GS. We anticipate the FocalPoint GS trial to be completed by the middle of 2003 and a submission will be filed with the FDA shortly thereafter. There can be no assurance that any of these proposed products will demonstrate clinical efficacy or receive the required regulatory approvals.

SlideWizard Product Line

Our SlideWizard product line consists of PC-based applications focused on the quantification of the nuclear DNA content of cells and the detection and quantification of specific molecules in cells or tissue sections (immunohistochemistry and immunocytochemistry assays), the management and archiving of images and patient information, the exchange of data via telepathology and the creation of comprehensive reports combining color images and patient data. Our SlideWizard line of products include:

- Telepathology Module: a module for the transmission and interpretation of high-resolution images captured at remote sites for teaching and research;
- Quantitative Image Cytometry-DNA: performs quantitative analysis of DNA by quantifying nuclear texture and morphology;
- Quantitative Image Cytometry-Immuno: offers general purpose image analysis that is ideal for recognition and quantification of virtually any stain application on a variety of biologic materials;

- A system to quantitatively assess the amount of up to three different absorption stains within the same microscopic slide, with some of the stains normally being related in a quantitative way to specific marker expressions;
- ImageTiter, a method to quantitatively measure abnormally high levels of antinuclear antibodies through "titration emulation" as indication for a variety of immune system problems; and
- SlideWizard, an electronic dotting and labeling system.

In November 1995, we received 510K clearance by the FDA to market the ImageTiter for automating antinuclear antibody testing. Our DNA and immuno-quantification applications are presently offered "For Research Only" in the United States. A SlideWizard workstation is also a component of the FocalPoint GS system that is currently sold only outside the United States. We expect to develop additional applications or modules in the field of tissue diagnosis and prognosis to run on the proprietary SlideWizard platform. We may elect to pursue regulatory clearance to market in the United States for additional SlideWizard applications currently under development or developed by us in the future.

Molecular Diagnostics Products

We are developing oncology products and services under our collaboration with BD. These products and services will be based upon genomic and proteomic markers identified through discovery research conducted at Millennium under its existing research and development agreement with BD. TriPath Oncology is clinically validating and will be developing these proprietary cancer markers into commercial diagnostic and pharmacogenomic oncology products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology. BD will continue to fund additional discovery research activities at Millennium, at least through the end of their agreement in early 2004, aimed at developing and commercializing molecular diagnostics and pharmacogenomic products and services for malignant melanoma and cancers of the cervix, breast, ovary and colon.

We are currently focused on developing molecular diagnostic and pharmacogenomic products and services for cancers of the cervix, breast, ovary and colon. Though we will discuss our expectations for our molecular diagnostic products throughout this section, there can be no assurance we will be successful in developing any products or services that will prove to have any clinical or therapeutic value to the healthcare system nor that we will be able to develop such tests in an economically viable way.

Cervical Staging Assay

The focus of the cervical oncology program is to develop and commercialize highly sensitive and specific novel gene/protein targets for the direct detection of pre-invasive high-grade disease (CIN2/3 and CIS) and invasive cervical cancer independent of age and HPV infection status. We will initially seek an indication for use to detect the presence of pre-cancerous disease and cervical cancer in women, regardless of age, who have tested positive for HPV when the HPV test is performed as part of a primary screen for cervical cancer and/or in women who have been diagnosed with ASCUS or LSIL by cytologic screening. By attaining a high level of clinical performance for both sensitivity and specificity, we believe that the resulting assay may improve the predictive value of both HPV and cytologic screening and, as a result, will reduce false-positive referrals to colposcopy while maintaining a high level of detection of high-grade disease and cervical cancer as compared to the current clinical standards. Addressing this medical decision point could lead to a substantial cost savings for the health care system (estimated at up to $2.3 billion per year) as well as a reduction in morbidity and discomfort associated with unnecessary medical procedures.

Breast Cancer Screening Assay

We are completing the discovery phase and early development of reagents for screening of breast cancer. This test will be a blood based, quantitative immunoassay targeted at the identification of multiple proteins specific for early stage breast cancer. We believe that by distinguishing those women who have an underlying

malignancy from those who do not will lead to reduced morbidity associated with the avoidance of unnecessary biopsies and result in significant savings to the health care system.

Breast Cancer Staging Assay

We are developing reagents for a slide-based test to quantify protein expression for multiple cancers for staging of breast cancer. This test will be formatted as a slide-based immunohistochemistry test that will utilize our proprietary SlideWizard system to quantify protein expression for multiple cancer markers. We believe that our breast cancer staging test will provide oncologists a more accurate approach to determine which patients are at highest risk of recurrence and require more aggressive treatment. Although a high percentage of early stage breast cancer patients are treated with adjuvant chemotherapy, a more accurate prediction of direct tumor behavior may help to guide the oncologists in their choice of therapies to administer.

Breast Cancer Monitoring Assay

We will utilize cancer markers discovered through our breast cancer screening program to develop a blood-based breast cancer monitoring test for the detection of early recurrence. The goal of our breast cancer monitoring program is to clinically validate the cancer markers discovered for the breast screening panel to detect early stage breast cancer recurrence in asymptomatic patients. The test will be used to monitor patients for response to treatment and to detect early recurrence post treatment. We believe that these changes in patient management will be result in improved health outcomes and increased patient survival.

Ovarian Cancer Screening Assay

We are completing the discovery phase and initiating development of a screening test for ovarian cancer. Our ovarian cancer screening test will be a blood-based immunoassay comprised of a panel of antibodies which will measure the expression of target proteins specific from early stage ovarian cancer. The test will be initially targeted for patients considered to be at high-risk patient for ovarian cancer, a market estimated at about 2 million cases per year in the U.S. Our ultimate goal is to validate the test as a means of routine screening of women aged 40 and older. By detecting ovarian cancer at an earlier stage of disease we believe that use of our test will lead to earlier initiation of treatment and increased patient survival.

Colorectal Cancer Screening Assay

We are completing the discovery phase and initiating development of a screening test for colorectal cancer. The colorectal cancer screening test will be a blood-based immunoassay comprised of a panel of antibodies which will measure the expression of target proteins to detect early stage colorectal cancer. We believe that our test will detect the pre-cursor adenoma polyps as well as early stage colorectal cancer. We will target the test for individuals considered at high risk for developing colorectal cancer. We believe that the test could ultimately be used as a general screening test for men and women aged 50 and older. By detecting colorectal cancer at an earlier stage of disease we believe that use of our test will lead to earlier initiation of treatment and increased patient survival.

Melanoma Staging Product

Through our agreements with BD and Millennium, we received distribution rights to a novel gene expression target for malignant melanoma shown in limited studies to be predictive of risk of metastasis in Stage I and Stage II melanomas. In February 2002, we executed a letter of intent to collaborate with AmeriPath, Inc., a leading national provider of cancer diagnostics, genomics, and related information, on the validation and clinical use of a novel gene expression assay for malignant melanoma. During 2002, AmeriPath developed and validated a "home brew" assay utilizing our novel Melastatin gene-based detection probe and our SlideWizard imaging and telepathology platform. We finalized this arrangement in late 2002 following the successful completion of a series of key development and validation milestones by the parties initiated during 2002. According to the terms of the agreement, we will supply AmeriPath with the novel gene-based probe

labeled as an ASR that will be incorporated into an *in situ* hybridization assay developed at AmeriPath. AmeriPath will initially offer the melanoma assay at its Center for Advanced Diagnostics facility located in Orlando, Florida. AmeriPath will have exclusive rights to the assay for clinical diagnostic testing services subject to certain milestones. The agreement further contemplates the initiation of additional research studies by the parties to more broadly assess the clinical significance of the novel melanoma gene.

An ASR was used in a laboratory developed assay for melanoma staging at the end of 2002. The introduction of ASRs that may be used in laboratory developed assays, including staging and prognostic assays for cervical and breast cancer, is expected in 2004. The introduction of ASRs that may be used in laboratory developed assays for the early detection and monitoring of ovarian, breast, and colon cancer is expected in 2005. In the interim, we are investigating a number of potential strategic alliances to complement, accelerate and augment the activities arising from our collaboration with BD.

We do not expect to generate any significant revenue from our molecular diagnostic products until 2005. Consequently, our oncology business unit will incur expenses in excess of revenues generated. Some of these expenses include the lease of several laboratories at BD's facility in Research Triangle Park, North Carolina. This arrangement substantially ended in July 2002 after we occupied newly equipped laboratory and office space in Research Triangle Park. We do, however, maintain several small laboratories at the BD facility.

In January 2003, we entered into an agreement with BMS to provide quantitative tissue based image analysis in support of BMS' oncology therapeutics programs. The goal of the initial program will be to assess the pharmacologic effect of a therapeutic agent targeted at treating epithelial cancers, including cancers of the cervix, breast and colon. Under the terms of the agreement, we will utilize our SlideWizard image analysis platform and proprietary software applications to provide a quantitative assessment of tumor marker expression levels for tissue samples taken from patients enrolled in a Phase I clinical trial. The data we generate will be used to evaluate patient response across varied dosing levels based on changes in tumor marker expression levels, both before and after treatment.

Finally, we believe that our automated visual intelligence technology can be developed for use for other diagnostic tests that involve microscopic analysis of biological specimens on glass slides, such as tissue, blood, urine, sputum or other samples. To develop our technologies for other applications, we will need to adapt software algorithms to analyze each of these other samples.

Marketing and Sales

Marketing Strategy

As the development and commercial engine of one of the broadest based gene discovery programs in cancer diagnostics in the world, we have a unique opportunity to change the clinical practice of medicine by developing and commercializing novel, molecular oncology tests that provide a more accurate, disease-specific understanding of cancer, thereby better addressing the needs of clinician medical practitioners and our primary customer, the patient. These tests will be used to screen and assist in the diagnosis of the presence of disease, to assess patient prognosis and outcome more accurately, to guide therapeutic selection in the management of certain cancers, and to monitor for disease recurrence.

Historically, diagnostic companies have focused on changing the laboratory practice of medicine, primarily through delivering the benefits of automation to laboratories worldwide. Today, virtually all sectors of the clinical diagnostics industry have been automated to a significant extent. The two exceptions to this pattern of rapidly increasing automation in *in vitro* diagnostics have been the cytopathology and histopathology laboratories, where the standard of practice is defined by the visual examination and analysis of cells and tissues. We believe our integrated cervical cytology screening solutions offer substantial value to our laboratory customers worldwide today, and that through continued focus on leveraging our assets and technologies towards the delivery of novel molecular oncology tests we will be well positioned to offer the best possible clinical solution for the patient.

Our marketing strategy is focused on providing solutions that address the unmet needs of our three broad market stakeholders: clinical laboratories, clinician and third-party payors. We increased our marketing efforts

during the first half of 2002 by directing resources toward various marketing-related initiatives designed to promote brand identification and awareness, increase market acceptance of our products and services and enhance product management. We have expanded our presence in the marketplace through increased advertising and promotion, company-sponsored seminars and trade shows, and peer selling activities. To further educate and reinforce the benefits of our products, we initiated a partnership with a third-party physician/peer selling organization in 2001 that continued into 2002. An important element of our marketing strategy is to achieve broad market acceptance of our integrated product consisting of our SurePath thin-layer slides for cervical cancer screening by the FocalPoint system. In implementing this strategy, we will seek to address the needs of the constituencies described below.

Clinician/OB-GYN.

In 2002, we initiated a number of key initiatives targeted at physician education activities including continuing medical education programs. In 2003, we will expand our physician educational programs for to access a broader and more focused segmentation. We will also conduct a number of clinician-related activities including the establishment of a Clinical Advisory Board and numerous expert panels as forums to discuss and receive feedback on unmet medical needs, standards of care, market trends, product concept review and use, and clinical trials strategies, etc. Finally, we will work toward cultivating and developing relationships with leading clinicians to identify current and future potential product areas with the goal of expanding peer-to-peer selling and influence.

Clinical Laboratory

The standard of practice in the cytopathology and histopathology laboratories is defined by the visual examination and analysis of cells and tissues. Cancer, in one of its many forms, is the disease most often considered and evaluated in laboratories. Samples being examined are typically tissue biopsies or Pap smears. The collection and preparation of these samples have been resistant to the general wave of automation because they have required human observation and analysis under a microscope. The observer is required to identify and interpret what are often very subtle changes within human tissues. These are often very complex, time consuming, tedious and exacting tasks. The practices of cytopathology and histopathology remain largely manual and labor intensive.

Previously, the complex biologic structural, or morphologic changes exhibited by cancer were considered too subtle for identification and interpretation by computer or other automated apparatus. The conventional wisdom was that cell and tissue diagnosis is an intrinsically qualitative process that requires subjective visual judgment. However, as the science of image processing and analysis has matured, it has become increasingly accepted that these "subjective" signals can be redefined in terms of mathematical algorithms. These algorithms, in turn, provide the basis for computerization and an automated solution.

As the last frontier for automation in *in vitro* diagnostics, the cytopathology and histopathology laboratories present a major opportunity. We believe that automation of these laboratories through computerized image analysis will:

- significantly reduce labor costs;
- drive improved standardization, reproducibility, and quality control;
- enhance the efficiency of treatment by increasing the accuracy and precision of diagnosis; and,
- provide an opportunity to collect digitized information to facilitate the development of highly specific and targeted outcome patient care programs.

Automated slide preparation and screening products were introduced into the cervical cancer screening market in the mid-1990s. We expect to benefit from the increased awareness and growing acceptance of these new technologies.

i^3 Series Product Line

We currently market our cervical cytology products as part of an integrated system and have combined them under our i^3 Series product line, as discussed above. Our SurePath, PrepStain and FocalPoint systems, together, provide the only integrated solution for sample preparation, processing, staining and computerized analysis of liquid based thin-layer preparations. We began limited international commercial sales of our PrepStain system in 1993, and commenced commercialization in the United States following FDA approval in 1999. We began placements of AutoPap QC systems, a predecessor to the current FocalPoint system, in 1995 and of the FocalPoint primary screening system in 1998. FocalPoint is the only fully automated Pap smear screening device to receive regulatory clearance for marketing in the United States for both thin-layer and conventional Pap smear slide preparations.

The principal market for gynecological applications of PrepStain and FocalPoint are clinical laboratories worldwide. Clinical laboratories are also the primary focus for patients, physicians and third party payers in connection with screening for cervical cancer. In an effort to facilitate the adoption of our products, we have engaged the necessary sales professionals to educate and promote our products to each of these groups. Furthermore, we have contractual relationships with organizations that provide physician education and third party payer/reimbursement support. We view these relationships as a necessary extension of our business given their potential to fuel our growth.

The principal market for non-gynecological applications of PrepStain is also clinical laboratories worldwide, although these applications are performed in significantly lower quantities than cervical cancer screening applications. Non-gynecological applications for the detection of cancer are performed on body fluids, including urine samples, respiratory specimens and a variety of fine-needle aspirates of specific organs.

Large clinical laboratories. Conventional Pap smear testing has become a concentrated market in the United States. We believe that approximately 50% of cervical cancer test volume is concentrated among a relatively small number of large laboratories. We believe the PrepStain's high throughput and cost-effectiveness and FocalPoint's ability to show improved specificity over conventional practice will enable us to market PrepStain and FocalPoint successfully to this concentrated market segment. Moreover, the pressures associated with rising health care costs, rising litigation costs, and the limited supply of qualified cytotechnologists should further facilitate adoption of PrepStain and FocalPoint by the large laboratory market.

On March 5, 2003, we announced that we had entered into a collaboration agreement with Quest Diagnostics Incorporated ("Quest"), the largest provider of diagnostic laboratory testing in the U.S. Under the terms of the agreement, Quest will begin offering our i^3 Series integrated solution for cervical cancer screening, including our SurePath test pack, our PrepStain slide processor, and our FocalPoint slide profiler in selected locations. Quest will evaluate the i^3 series relative to its immediate and future needs for cervical cancer screening. In addition, it has installed our Tele-pathology™ system in two locations and is currently evaluating various aspects of the system's utility. There can be no assurance that our agreement with Quest will generate significant revenue. Nor can we assure that Quest will find our products and services as effective and efficient in their network of operations.

Academic Centers of Excellence. We expect to continue to build a "franchise" among academic centers of excellence and to continue to add high profile, opinion leaders to our customer list. We believe these relationships reflect on the quality of our products. Further, as early adopters of new diagnostic technologies, the academic centers of excellence will be key targets for the early introduction of our molecular diagnostic products.

Medium and small clinical laboratories. We also intend to continue to devote a portion of our marketing and sales resources to targeting medium-sized and small clinical laboratories, including, in particular, laboratories that serve hospitals and local and regional integrated health care provider networks. These laboratories are often well integrated into the local health care management process and delivery continuum and, therefore, facilitate an integrated sales process that includes the ordering clinician, the laboratory, and the payer. This is of particular significance to our strategy for commercializing molecular diagnostic and pharmacogenomic products and services that will require significant interaction between the

laboratory and the clinician. We expect that the medium-sized and small clinical laboratory segment of the market will generally utilize our equipment rental programs.

Third-party payers. We have gained a significant level of market acceptance for our products by third-party payers by devoting additional resources to the area of reimbursement. We plan to continue promoting the clinical and economic benefits of PrepStain and FocalPoint systems to managed care companies , major private insurers and other third-party payers. We have demonstrated that the overall cost savings to the health care system, resulting from the early detection of cervical cancer and the decrease in unnecessary repeat Pap smears, biopsies and colposcopies resulting from improved specimen adequacy, more than offset the cost of our products. See also "Third-Party Reimbursement" below.

Molecular Diagnostic Products

The marketing strategy for the molecular diagnostic products we are developing is predicated on several key principles. First, our marker discovery programs are all driven by clinical specifications developed from an ongoing analysis of the current standards of care for cancer of the cervix, breast, ovary and colon. From these analyses, we have identified areas of clinical need and, therefore, market opportunity. Second, our product development strategy comprehends minimal disruption of laboratory workflow and current practice. We are designing our products to change the clinical practice of medicine, not the laboratory practice of medicine. Third, we employ a strategy for commercialization that includes stacking clinical claims in which we will initially target defined clinical problems in defined patient populations to create specific and clearly defined clinical outcomes. Our strategy comprehends the fact that the commercial opportunity associated with our products will depend on the extent to which they impact decisions made and actions taken in the course of the early detection and clinical management of cancer, and that the value generated by these products and the attendant level of reimbursement derived from third-party payers will reflect the extent to which the products positively impact patient outcome, both clinical and economic. Fourth, we will employ a strategy for early commercialization that includes initial introduction of analyte specific reagents to be used in laboratory developed assays. Fifth, we will leverage the recognition, relationships, and infrastructure developed to market and sell our i^3 Series cervical cytology product line to commercialize our molecular diagnostic products. In effect, the infrastructure we have developed for our cervical cytology product line will serve as a conduit for our molecular diagnostic products.

Sales Strategy

i^3 Series Product Line

We generate PrepStain revenue from either the sale, rental or lease of PrepStain systems and from the sale of the related SurePath and PrepStain test kits, comprised of proprietary reagents and other disposables. Additionally, we generate revenue from service contracts on the PrepStain systems. For system sales, customers purchase the PrepStain instrument and make separate purchases of SurePath and PrepStain test kits. We recognize revenue on sales of the PrepStain system at the time the system is installed and accepted at the customer site. For system rentals, also known as reagent rentals, we place PrepStain systems at the customer's site free of charge and the customer is obligated to purchase SurePath and PrepStain test kits for a fixed term, typically three or four years. Under these transactions, there is no revenue recognized on the PrepStain system hardware. For system leases, we offer two alternatives. The first alternative involves a lease arrangement through which we lease the PrepStain system directly to the customer. These leases require monthly payments for the system and are typically for 36 or 48-month terms. The customer purchases the SurePath and PrepStain reagents and disposables that run on the system separately from the lease on an as-needed basis. Under these transactions, there is no up front revenue recognized on the PrepStain system hardware. The second alternative is known as our "IPO program", under which PrepStain systems are purchased by a third party financial institution and are placed at the customer's site free of charge. The customer then purchases the SurePath and PrepStain reagents at a price that is sufficient to repay the financial institution for the cost of the PrepStain system and to provide us with an acceptable profit on the reagents and disposables. Under the IPO program, we record revenue for the system sale at the time the system is installed and accepted at the customer site. Since 2001, our strategy has been to emphasize in-house reagent rentals in

an effort to permit us to retain a greater percentage of the ongoing, higher margin PrepStain reagent revenue stream. Regardless of whether PrepStain systems are sold, rented or leased, however, each system placed typically provides a recurring revenue stream as customers process our SurePath test packs.

We generate FocalPoint related revenue from the direct sale of FocalPoint systems and from the placement of FocalPoint systems under fee-per-use contracts. In the latter case, fee-per-use revenue commences in the month a system is initially placed in commercial use at a customer site and consists of per-slide monthly billings, fixed rental billings, or certain fee-per-use contracts that require minimum payments. Domestic customers may also elect to lease the FocalPoint system under the IPO program. Additionally, we generate revenue from service contracts on FocalPoint systems. We have and will continue to consider arrangements that may involve the placement of FocalPoint systems at customer sites free of instrument charge for increased commitments to purchase our SurePath and PrepStain test kits.

We also generate revenue from either the sale or rental of our SlideWizard line of products and from service contracts on these products. For system sales, customers purchase the products through distributors in countries where such relationships exist. Where distributor arrangements do not exist, we sell these products directly to the customer.

Marketing and Sales Organizations

We currently utilize in excess of 100 full-time marketing and sales personnel worldwide to market, sell and provide post-sale support of our products. In addition to expanding our existing cervical cytology business, our intention is to leverage our existing sales and marketing capabilities, our strong relationships with key influential leaders in the anatomic pathology laboratory and clinician segments, our customer base among the academic institutions to pioneer the acceptance of imaging and to accelerate the adoption of analyte specific reagents for laboratory developed assays in the second half of 2004.

In the U.S., we have expanded our efforts to market our cervical cancer screening products through a direct sales organization focused both on the physician, primarily OB-GYN and primary care physicians, and laboratory market segments to optimize awareness and market penetration of our products. Through an alliance with Nelson Professional Sales ("NPS") begun in late 2000, we targeted the physician market directly for the first time by adding clinician sales representatives on a contract basis, to augment our laboratory sales efforts. The NPS relationship allowed us to quickly establish a selling presence external to the laboratory and has served us well. In April 2002, we terminated the agreement with NPS, simultaneously extended offers of employment to the majority of the physician representatives and created a direct physician sales force as a critical element of our commitment to better focus on the needs of our clinician customers. Concurrent to this effort, we consolidated our laboratory and clinician sales organizations under a single management umbrella to promote efficiency and effectiveness. We have a team of field based reimbursement specialists who call on U.S. managed care organizations and other third-party payers to achieve maximum reimbursement levels and to further stimulate demand for our products. Where appropriate, we also seek co-marketing agreements with major clinical laboratories to leverage their sales capabilities and more effectively market our products directly to health care providers.

Outside the U.S., with the exception of Canada where we sell to and service customers through our own sales and service organization, we market and sell our products primarily through a distribution network. To support these efforts, we employ eight full-time personnel, consisting of a sales director, sales and marketing professionals, managers and post-sales support personnel located in Europe. Our international distribution network is comprised of both large distribution organizations with products focused on the clinical diagnostic market and smaller organizations with products focused specifically on the anatomic pathology market.

We offer post-sale support services, including customer training, product installation, telephone technical support and repair service directly to customers in the United States. Our support personnel are located both at our headquarters and in select major metropolitan areas. Internationally, we provide these services through our employees and distributor organizations.

Manufacturing

FocalPoint

We currently assemble, integrate and test the electronic, mechanical and optical components and modules of FocalPoint at our Redmond, Washington facility. Our operations have produced sufficient FocalPoint systems to meet customer demand since we began commercial operations in 1996 and we believe we have sufficient capacity to meet anticipated near-term customer needs for our FocalPoint and PrepMate products.

We purchase all components for the FocalPoint system from outside vendors. Several components of the FocalPoint system are supplied by sole-source vendors. If any of these sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers. We may be unable to quickly establish additional or replacement sources of supply for several FocalPoint components. In addition, we may need to obtain regulatory approval to substitute certain components.

PrepStain

We currently assemble, test and package components of PrepStain at our manufacturing facility in Burlington, North Carolina. We also manufacture our SurePath preservative fluid and our PrepStain line of reagents and stains for PrepStain at the Burlington facility. We manufacture PrepMate, the front-end accessory to the PrepStain, at our Redmond, Washington facility. We believe that our existing manufacturing and assembly processes are adequate to meet the near-term, full-scale production requirements of our SurePath and PrepStain systems for cervical cancer screening.

We purchase certain PrepStain instrument components from a single supplier in Europe. The consumable items used with PrepStain are purchased from a variety of third-party vendors, some of which are sole-source suppliers. We have a multi-year, exclusive contract with the supplier of manufactured instrument components that are incorporated into our PrepStain product line, which expires in December 2004. Pricing for components is fixed, but is subject to adjustment based upon changes in raw material costs. Our obligation to use this supplier exclusively for the components is contingent upon this supplier supplying us at prices competitive with those offered by third parties on similar terms, and upon this supplier meeting our quality and production requirements. We believe that the supplier has sufficient capacity to meet our present and future requirements for these components through the end of 2004. To address the time beyond that date, we are undertaking development activities to ensure uninterrupted supply of PrepStain component parts.

Lean Manufacturing Strategy

During 2002, we reorganized our operations group, adding management expertise in Lean Manufacturing. Our Lean Manufacturing strategy incorporates process improvement methodologies to eliminate non-value adding activities within the operations area to reduce costs, improve quality and product delivery. The Lean Manufacturing process improvement strategy includes tools such as Value Stream Mapping, Kanban Materials Management and Flow Velocity®. In July 2002, we successfully completed our first kaizen event in support of Lean Manufacturing implementation. Value stream driven kaizen events now occur regularly, at a rate of at least one per month. We believe these efforts will continuously remove waste and inefficiencies from our manufacturing processes resulting in lower costs, improved quality and delivery to our customers.

SlideWizard Products

We currently manufacture the majority of our SlideWizard product line at our Burlington, North Carolina facility. We also manufacture a limited number of our SlideWizard instruments and integrate them into the FocalPoint GS at our Redmond, Washington facility. We believe we have sufficient capacity to meet anticipated near-term customer demand for our SlideWizard product line.

Our SlideWizard products consist primarily of off-the-shelf components and proprietary software. The components are supplied by a variety of vendors, some of which are sole-source suppliers. We have been integrating and selling SlideWizard products since 1993.

Molecular Diagnostics

Reagents for our Melastatin detection probe are manufactured by BD. We believe BD has adequate capacity and production capability to satisfy customer demand and technical product requirements. We will consider in-house or third-party manufacturing of additional molecular diagnostic reagents that we develop. Our imaging platform hardware will consist primarily of standard, off-the-shelf, components available from a number of different suppliers. Integration of the components, software loading and final testing will be conducted at our manufacturing facility in Burlington, North Carolina.

Our Suppliers

Several components of our products are supplied by sole-source vendors. Subject to any of our exclusive contractual arrangements, we may seek to establish relationships with additional suppliers or vendors for components of our products. If any of our current or future sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers for use in our products. We may be unable to quickly establish additional or replacement sources of supply for several of these components. The incorporation of new components, or replacement components from alternative suppliers into our products may require us to submit PMA supplements to, and obtain further regulatory approvals from, the FDA before marketing the products with the new or replacement components. There can be no assurance that we will be able to obtain the necessary approvals.

Manufacturing Standards

Our manufacturing process is subject to extensive regulation by the FDA, including the FDA's Quality System Regulation ("QSR," also known as Good Manufacturing Practice, or "GMP") requirements. As part of the FDA regulatory process, we face periodic FDA inspections and other periodic inspections by U.S. and foreign regulatory agencies. See "Governmental Regulation." Both the Burlington, North Carolina and Redmond, Washington facilities are subject to periodic FDA inspections. Failure to comply with the FDA's QSR requirements in the future would materially impair our ability to achieve or maintain commercial-scale production. In addition, if we are unable to maintain full-scale production capability, acceptance by the market of PrepStain, SurePath and FocalPoint would be impaired, which in turn would have a material adverse effect on our business.

In addition to QSR requirements, we are required to meet requirements relating to ISO 9001 certification, including European regulatory requirements. A European "CE" certification is required to successfully sell PrepStain and FocalPoint in Europe according to certain directives of the European Union. The addition of other European directives may require us to further demonstrate compliance with new or modified requirements in order to apply the CE mark specific to those directives. The OEM supplier of the PrepStain instrument components has ISO 9001 certification and has obtained CE certification for the main PrepStain component. We obtained CE compliance for the entire PrepStain system. The FocalPoint System is certified to EN55022:94/CISPR 22, Class A, EN 50082-1 92, AS/NZS2064/CISPR 11, Class A.

We obtained ISO 9001 certification at our Burlington, North Carolina facility in 1999. Compliance audits were conducted on our Burlington, North Carolina facility by a certified ISO auditor in May 2000, January 2001, June 2001, January 2002, June 2002 and December 2002. We have no outstanding deficiencies related to these compliance audits. In addition, the Burlington and Redmond manufacturing facilities are undergoing additional ISO 13845 and 13488 certification audits in order to comply with Canadian requirements, which became effective on January 1, 2003. Under the Canadian requirements, third-party certification of compliance with ISO 13845 and 13488 and Regulation SOR/980282, as amended, is required.

We plan on transferring the manufacture of our PrepMate accessory to our Burlington, North Carolina facility after we have received FDA approval to do so. In contemplation of this transfer, our Burlington facility was inspected by the FDA in late 2002. We have sufficient capacity in our Redmond, Washington manufacturing facility to maintain an adequate supply of PrepMate units until approval is received.

Research and Development

Development of Molecular Diagnostic and Pharmacogenomic Products and Services

Our research and development programs are currently focused on four major goals:

- development of molecular diagnostic and pharmacogenomic products and services for malignant melanoma and cancer of the cervix, breast, ovary, and colon through our collaboration with BD.
- continued improvement and streamlining of the FocalPoint and FocalPoint GS products;
- additional enhancement of the PrepStain system, including adjunctive testing using the SurePath preservative solution, improvement of related PrepStain reagents and disposables, and further streamlining and automating the PrepStain slide processor with regard to the preparation and handling process; and
- development of additional SlideWizard applications with scalable automation capabilities to support our molecular diagnostic programs , as well as the needs of potential strategic partners.

TriPath Oncology is developing molecular diagnostic and pharmacogenomic products and services for malignant melanoma and cancer of the cervix, breast, ovary, and colon through our collaboration with BD. The goal of this research and development program is to develop products that are designed to identify cancer at its earliest stage and provide individualized diagnostic and prognostic information for patients with cancer. We are also seeking alternative applications for our technologies through internal research and development, as well as through strategic partnerships with other companies.

We completed the relocation of BD's molecular oncology program to temporary facilities in North Carolina at the end of December 2001. In January 2002, we signed a multi-year lease for approximately 22,000 square feet of laboratory and office space to principally house our TriPath Oncology operations. This space was occupied by TriPath Oncology personnel in July 2002. TriPath Oncology has assumed complete responsibility for both assay and instrument development-related activities.

We introduced an ASR that was used in a laboratory developed assay for malignant melanoma in the fourth quarter of 2002 through our collaborative agreement with AmeriPath, the largest provider of skin pathology services in the United States. We completed marker discovery and initiated the development of molecular assays for cervical and breast cancer in the third quarter of 2002. We anticipate the introduction of ASRs that may be used in laboratory developed tissue and cell based assays for the staging of cancer of the cervix and breast in 2004.

Our product development process for molecular assays begins with the identification and validation of genomic molecular markers specific to predetermined clinical outcomes and specifications. This discovery process, conducted at Millennium, is based on gene profiling technology that identifies genes which are uniquely over or under-expressed in our targeted patient populations. Multiple genes have now been identified for each of our oncology programs, and it is the unique combination of genetic markers that we believe will allow us to develop tests to improve the early detection of cancer and provide more individualized prognostic information for patients diagnosed with cancer.

Following gene discovery and initial pre-clinical validation at Millennium, this genomic information is transferred to the TriPath Oncology R&D organization to begin assay development. Our ultimate goal is to change clinical practice, not laboratory practice. As such, all of our assays are being developed in commercially accepted formats to facilitate rapid laboratory adoption. Our cancer screening assays are being formatted as immunoassay (IA) tests that are capable of detecting and quantifying multiple secreted markers (proteins) in blood. Our staging and prognostic assays will be slide-based utilizing tissue and cytology

samples, and will allow for precise quantification of molecular markers (proteins) within the context of tissue and cellular morphology. For the tissue-based assays, we are utilizing a standardized, slide-based immunohistochemistry (IHC) format with colorimetric bright-field detection. IHC has been routinely practiced in histology and cytology labs for many years and most labs are equipped with fully automated staining platforms. For our cell-based assays, we have adapted the IHC protocol into a slide-based immunocytochemistry (ICC) format, also with colorimetric bright-field detection.

All of our assay technology formats (IA, IHC and ICC) require monoclonal antibody reagents that will bind specifically to the proteins (markers) which are uniquely expressed by the genes identified by Millennium. These antibody reagents are produced and screened at TriPath Oncology in a high throughput format using our proprietary technology. We first translate the unique gene sequences identified by Millennium into antigens using state-of-the-art protein expression systems. These antigens are then used to produce specific monoclonal antibodies using mice immunization and cell culture technology. Each monoclonal antibody is independently validated using clinical samples with known patient outcome, and markers which are selected will be combined into a panel which will be optimized for assay sensitivity and specificity.

The final step in the development process is to link the molecular assays to our proprietary image analysis platform. We believe that clinical outcomes will be determined by subtle differences in gene or protein expression, and that these subtle differences in gene and protein levels will require advanced imaging capability for precise quantification and interpretation. Furthermore, we believe that tissue architecture, cell morphology, and precise sub-cellular localization of molecular markers will be an important tool for accurate cancer staging and prognosis. Therefore, we will adapt our proprietary image analysis platform to our molecular assays to allow analysis and quantification of multiple, discrete molecular markers within the context of tissue distribution and cellular location.

We are also leveraging our proprietary imaging technology to develop new collaborations to expand our commercial opportunities. In early 2003, we entered into an agreement with BMS to provide quantitative tissue based image analysis in support of their oncology therapeutics programs targeted at treating epithelial cancers including cancer of the cervix, breast and colon. We are utilizing our SlideWizard image analysis platform and proprietary software applications to provide a quantitative assessment of tumor marker expression levels from tissue samples provided by BMS for patients enrolled in a Phase I clinical trial. The data generated by our work will be used to evaluate patient response across varied dosing levels based on changes in tumor marker expression levels, both before and after treatment.

Improvement of FocalPoint, FocalPoint GS and PrepStain Products

Enhancements to both FocalPoint and PrepStain are specifically designed to increase the instruments' efficiency, ease of use, reliability and cost-effectiveness. This also includes initiatives directed at extending the shelf life of the SurePath and PrepStain lines of reagents and preservatives used with the PrepStain system. We also plan to explore alternative uses for adjunctive testing using our SurePath preservative fluid and to seek approval for the use of alternative collection devices in connection with the specimen collection process related to the PrepStain system.

Development of Additional SlideWizard Applications

We are continually enhancing our SlideWizard line of products. We have expanded this product line to a modular concept which allows rapid prototyping and product development. The degree of automation for the resulting applications can be adjusted to the needs of the corresponding market, from interaction to complete automation. This technology takes advantage of our intellectual property portfolio and will be primarily applied to complement the existing portfolio of applications with new developments focused on gene or protein based cancer staging and prognostic testing.

There can be no assurance that any product enhancement or development project that we undertake, either currently or in the future, will be successfully completed, receive regulatory approvals or be successfully commercialized. The failure of any such enhancement or project to be completed, approved or commercial-

ized could prevent us from successfully competing in our targeted markets and could have a material adverse effect on our business.

As of December 31, 2002, we had approximately 70 employees engaged in research and development activities. Our expenditures for research and development were approximately $8.8 million, $7.3 million, and $8.5 million for the years ended December 31, 2000, 2001 and 2002, respectively. See additional discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations." (Item 7.)

Third-Party Reimbursement

i^3 Series

The vast majority of private third-party medical insurance providers and governmental agencies offer reimbursement for laboratory testing associated with routine medical examinations, including Pap smears as part of a wellness program. In the United States, the level of reimbursement by those third-party payers for Pap smears varies considerably. On average, since many payers benchmark coverage and pricing determination based on Medicare, there has been a general increase in reimbursement amounts due to recent minimums established by the Center for Medicare and Medicaid Services ("CMS") which administers Medicare (formerly known as Health Care Financing Administration, or HCFA). Third-party healthcare payers in the United States are increasingly sensitive to containing healthcare costs and heavily scrutinize new technology. Third-party payers may also influence the pricing or perceived attractiveness of our products and services by regulating the maximum amount of reimbursement they provide. Successful commercialization of PrepStain and FocalPoint for cervical cancer screening in the United States and some other countries will depend on the availability of reimbursement from such third-party payers. Because the up-front costs of using our products are typically greater than the cost of the conventional Pap smear, we have worked to convince third-party payers that the overall cost savings to the health care system, resulting from early detection of cervical cancer and its precursors will more than offset the cost of our products.

We have focused on obtaining coverage and reimbursement from major national and regional managed care organizations and insurance carriers throughout the United States. In early 1998, we established a reimbursement team to work with third-party insurers and managed care organizations to establish and improve third-party reimbursement rates for our products. Most third-party payer organizations independently evaluate new diagnostic procedures by reviewing the published literature and the Medicare coverage and reimbursement policies on the specific diagnostic procedures. To assist third-party payers in their respective evaluations of PrepStain and FocalPoint, we provide scientific and clinical data to support our claims of the safety and efficacy of our products. We focus on improved disease detection and long-term cost savings benefits in obtaining reimbursement for PrepStain and FocalPoint for cervical cancer screening.

To date, the PrepStain thin-layer slide preparation procedures have achieved almost universal coverage from third-party payors, as has the FocalPoint procedure for the primary screening of conventionally-prepared slides. Since the combined procedures of the PrepStain and FocalPoint, as part of the i^3 Series represent an enhancement over the individual procedures themselves, we anticipate a similar acceptance from third-party payers for i^3Series and a general compliance with the CMS Medicare pricing and coverage determination.

In a Program Memorandum to Regional Intermediaries/Carriers dated March 14, 2001, CMS announced it had established National Limitation Amounts ("NLA") for the CPT reimbursement codes that relate to our products. CMS set the NLA at $28.31 for the manual screening (CPT code 88142) and re-screening (CPT code 88143) of each liquid-based, thin-layer prepared using the PrepStain system.

For conventional Pap smears screened by the FocalPoint system, the national limitation amount ("NLA") is $15.90 for each sample which falls within the category of slides classified as "within normal limits" and requiring no further review, or up to 25% of all slides screened (CPT code 88147). The NLA for the remaining 75% or more of the slides screened using the FocalPoint system and requiring further review (CPT code 88148) is $21.23. We do not believe these limits will adversely impact our current pricing strategy or reduce the demand for our products.

In October 2002, the American Medical Association ("AMA") published its official and most comprehensive coding resource, "CPT Professional 2003." Included in the publication are two new cytopathology CPT codes, 88174 and 88175. These two new codes for automated thin layer preparation screened by an automated system had been announced by the Centers for Medicare & Medicaid Services ("CMS") in September 2002. These CPT codes are applicable to the combined use of our SurePath slides screened using our FocalPoint slide profiler. To our knowledge, we are presently the only company to offer laboratories an FDA-approved automated screening system that can be utilized to evaluate both thin-layer slide preparations and conventional Pap smears on a single computerized platform. The NLA for the new codes was "cross-walked" from the previous pricing structure for conventional smears and was recommended at up to $29.85 for the "No Further Review" category and up to $37.01 for the "Review" category; both levels represent a premium to the current $28.31 national limitation rate for manually screened thin-layer slides. CMS issued a Program Memorandum ("PM") with instructions on the 2003 Clinical Laboratory Fee Schedule to its carriers and intermediaries on November 8, 2002. The PM is available on CMS' website. This PM includes the final payment determinations for the new tests performed under the new CPT codes. The 2003 Medicare Clinical Laboratory Fee Schedule became effective for services delivered from January 1 to December 31, 2003.

Typically, third party reimbursement for laboratory testing is based upon the level of technical complexity required to perform the test. When new tests are introduced, laboratory managers will typically select from the existing CPT codes that best describe the test procedure. In those instances where existing CPT do not adequately describe the test or support the cost of performing the procedure, manufacturers may apply for new CPT codes that, when granted, are assigned NLAs as described above. Although we are developing our novel molecular oncology assays in standard technology assay formats to accelerate laboratory acceptance, it is likely that existing CPT codes may not adequately describe our tests or support the cost of performing the procedures. For each of our molecular oncology products we are conducting analyses to assess the appropriateness of multiple CPT coding scenarios based on existing CPT codes. In addition, we are developing economic models to measure the cost-benefit to third party payers to support the implementation and use of our tests. Based on the results of these analyses we will determine whether we will seek to apply to CMS for new CPT codes as described above.

Proprietary Technology and Intellectual Property

We currently hold over 110 issued or allowed United States patents and have six United States patent applications pending. We also hold over 100 foreign patents and have applied for patent protection for certain aspects of our technology in various foreign countries. We acquired many of these patents in the merger of AutoCyte and NeoPath and the acquisition of the intellectual property and technology of Neuromedical Systems, Inc. We further expanded our patent portfolio through the acquisition of the intellectual property of Cell Analysis Systems from BD in September 1999. Our patents cover system components, such as the disaggregation syringe, the PrepStain process, and various aspects of our high-speed image-interpretation technology, as applied to cytopathology and histopathology. Because of the substantial length of time and expense required to bring new products through development and regulatory approval to the marketplace, we rely on a combination of patents, trade secrets, copyrights and confidentiality agreements to protect our proprietary technology, rights and know-how. We intend to continue to pursue patent protection where it is available and cost-effective, both in the United States as well as in other countries. Most of our existing United States and foreign patents will expire between 2012 through 2019. A few of our foreign patents will expire as early as 2003. There can be no assurance, however, 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 our competitors.

Our molecular oncology program focuses on developing and commercializing diagnostic and pharmacogenomic tests to improve the early detection and clinical management of cancer. The core products we are developing through our collaboration with BD will be based upon proprietary genomic and proteomic markers identified through discovery research, conducted at Millennium, under its existing research and development agreement with BD. We have sublicensed certain of BD's rights to the proprietary markers. We

will identify and clinically validate novel molecular marker panels, which will be used in developing molecular assays which will produce molecular profiles descriptive of clinical phenotype and patient outcome. Multiple genes have now been identified for each of our oncology programs, and it is the unique combination of the genetic markers that we believe will allow us to develop tests to improve the early detection of cancer and provide more individualized prognostic information for patients diagnosed with cancer. We will seek United States and foreign patent protection for the molecular marker panels that we discover and other inventions based on the markers and our product development process.

Under current law, patent applications in the United States and in foreign countries are generally maintained in secrecy for a period after filing. The right to a patent in the United States is attributable to the first to invent, not the first to file a patent application. 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 patents or proprietary rights of third parties. There can be no assurance that a court would rule that our products do not infringe other third-party patents or would invalidate such third-party patents. We may incur substantial legal fees in defending against a patent infringement claim or in asserting claims of invalidity against third parties.

In the event that we are determined to be infringing any claims of third-party patents and such claims are upheld as valid and enforceable, we may be required to pay damages, prevented from selling our products, required to obtain a license from the owners of such patents or 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 attempt to redesign our products or processes to avoid infringement. Our failure to obtain these licenses or to redesign our products would have a material adverse effect on our business, financial condition and results of operations.

We have entered into confidentiality agreements with all of our employees who we believe should sign such agreements, and several of our consultants and third-party vendors. These agreements also require employees and consultants to disclose to us ideas, developments, discoveries or inventions they conceive during employment or consultation. They also must assign any proprietary rights in any inventions conceived or developed while employed by us if such relate to our business and technology. These agreements may not provide meaningful protection for our confidential information if there is unauthorized use or disclosure of our proprietary information. There can be no assurance that the obligations of our employees and consultants and third parties with whom we have entered into confidentiality agreements to maintain the confidentiality of trade secrets and proprietary information will effectively prevent disclosure of our confidential information. There also can be no assurances that our trade secrets or proprietary information will not be independently developed by our competitors.

We have registered trademarks in the United States for AutoCyte®, AutoCyte Quic®, AutoPap®, CytoRich®, ImageTiter®, PapMap®, PrepMate®, SlideWizard®, and TriPath Imaging®. We have pending U.S. trademark registrations for i^3 Series™, FocalPoint™, PrepStain™, SurePath™, TriPath Care Technologies™, and TriPath Oncology™. International registered trademarks are maintained in Argentina, Australia, Brazil, Canada, Chile, China, European Union, Hong Kong, Indonesia, Israel, Japan, Malaysia, Mexico, Russian Federation, Singapore, South Africa, Switzerland, Taiwan, and Thailand for several of our trademarks. We are currently pursuing international trademark registrations for FocalPoint™, PrepStain™, SurePath™, and TriPath Care Technologies™. In addition to trademark activity, we issue a copyright notice on all of our documentation and operating software. There can be no assurance that any trademarks or copyrights that 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, to enforce patents, trademarks and copyrights, or to protect trade secrets and could result in substantial cost to, and diversion of effort by us. There can be no assurance that we would prevail in any such litigation. 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

Commercial Operations

The cervical cancer screening market is comprised of the conventional Pap smear process and certain technologies that have been introduced in recent years, or are currently under development to provide improvements over the conventional Pap smear process. Our competitors in the development and commercialization of alternative cervical cancer screening technologies include both publicly traded and privately held companies. Alternative technologies known to us have focused on improvements in slide sample preparation, the development of automated, computerized screening systems and adjunctive testing technologies. Nevertheless, some competitors' products have already received FDA approval and are being marketed in the United States. In addition, one of our competitors has greater financial, marketing, sales, distribution and technical resources than us, and more experience in research and development, clinical trials, regulatory matters, customer support, manufacturing and marketing.

We believe that our products compete on the basis of a number of factors, including slide specimen adequacy, screening sensitivity, ease of use, efficiency, cost to customers and performance claims. We believe a fully automated solution incorporating collection, preparation, staining, and computerized imaging for liquid based thin-layer preparations is required for sustaining our competitive advantage. While we believe that our products will have competitive advantages based on some of these factors, there can be no assurance that our competitors' products will not have competitive advantages based on other factors, including earlier market entry, which may adversely affect market acceptance of our products. Moreover, 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. Our products could be rendered obsolete or uneconomical by technological advances of our current or potential competitors, the introduction and market acceptance of competing products, or by other alternative approaches for cervical cancer screening.

Our primary competitor in thin-layer slide preparation is Cytyc Corporation. Cytyc's systems, the ThinPrep 2000 and ThinPrep 3000 Processors, are based on a membrane-filtration separation system rather than the density gradient and centrifugation approach used in our PrepStain process. The Cytyc ThinPrep systems are presently the only other thin-layer sample preparation systems approved by the FDA as a replacement for the conventional Pap smear. They are also used for non-gynecological applications. Additionally in Europe there are a few small thin-layer competitors offering a manual method liquid based product. Currently these manufacturers have very little market share and are not actively pursuing FDA approval for their products. Nonetheless, they are creating competitive activity in France and in several other countries.

In addition, in October 1996, Cytyc originally announced a non-exclusive co-marketing agreement (subsequently made exclusive) with Digene Corporation. In September 1997, the FDA approved PMA supplements submitted by Cytyc and Digene enabling testing for HPV directly from Cytyc's ThinPrep process cell suspension. We began working with Digene on a PMA supplement application for use of our SurePath cell suspension with Digene's HPV test in the United States. In July 2002, Digene informed us that it had received a "not approvable" letter from the FDA for its Pre-Market Approval Supplement application to use our SurePath test pack as a specimen collection medium for its Hybrid Capture® 2 (hc2) HPV DNA Test. We are working with Digene and have taken a leadership role in discussions with the FDA to resolve and respond to the issues identified in the letter. We remain hopeful that resolution of the issues identified by the FDA will not significantly alter our expectations for submission to the FDA in mid-2003. Failure to obtain this approval, however, will likely impact our ability to most effectively compete in the liquid-based Pap smear testing market. In Europe, our SurePath product is already in routine use with Digene's HPV test.

In January 2000, Cytyc and Quest Diagnostics announced a multi-year agreement naming ThinPrep as the exclusive liquid-based cervical cancer screening methodology for Quest. Exclusivity related to this agreement expired in December 2002. In October 2000, Cytyc announced an exclusive U.S. strategic alliance for women's health with Roche Diagnostics. In 2002, Cytyc announced that exclusivity related to this agreement had been discontinued. Further, in January 2001, Cytyc announced an exclusive co-promotion

agreement with Digene surrounding the use of Digene's HPV test using the Cytyc preservative solution. It is our understanding that this agreement expires in June 2003.

In February 2002, Cytyc and Digene announced their intention to merge. The proposed transaction was subject to review by the U.S. Federal Trade Commission ("FTC") under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. On June 24, 2002 the FTC authorized staff to seek a preliminary injunction to block the merger. Cytyc subsequently terminated its merger agreement with Digene on July 1, 2002.

We also face several competitors, or potential competitors, in the imaging field. To date, the FocalPoint system is the only FDA-approved device for the automated primary screening of PrepStain, thin-layer and conventional Pap smear slides. In December 2002, Cytyc announced that it had received an "Approvable Letter" from the FDA for a computer assisted device for use with slides prepared using its slide preparation systems. An Approvable Letter usually represents the final step before a product receives FDA clearance for marketing in the United States. In the letter, the FDA stated that the application for Cytyc's imaging system is approvable subject to the FDA's inspection of Cytyc's manufacturing facility. Other competitors include ChromaVision Medical Systems, Inc., which develops, manufactures and markets an automated cellular imaging system to assist in the detection, diagnosis and treatment of cellular diseases such as cancer and infectious disease, and Applied Imaging Corporation, which develops and markets automated genetic testing systems and imaging systems used in cancer pathology and research which are capable of sending digital images electronically for remote review and consultation. In 2002, ChromaVision entered into an agreement with Ventana Medical Systems, Inc., to co-market their imaging device with Ventana's test for detection of human papilloma virus in slides prepared from cervical smears.

TriPath Oncology

Competition in the field of cancer diagnostic products is concentrated in a few areas and is expected to further intensify. Aside from mammography screening for breast cancer, the *in vitro* cancer diagnostics market consists primarily of tumor marker immunoassays. The cancer immunoassay market encompasses a number of blood-based tumor marker tests that are utilized extensively to assess therapeutic response and monitor for disease recurrence but have limited applications for screening due to their lack of sensitivity and specificity. Currently, prostate specific antigen (PSA) is the only blood based tumor marker that is universally utilized for cancer screening. Among the companies competing in the tumor marker immunoassay market are Abbott Diagnostics, Bayer Diagnostics, Roche Diagnostics, Ortho Clinical Diagnostics, Beckman-Coulter and Dade-Behring.

We believe that genomic and proteomic-based assays will likely provide a more accurate, disease-specific understanding of cancer to improve the clinical management of cancer. Although there are a number of companies that are investing in genomic and proteomic discovery research, few have invested as broadly in the cancer diagnostics area as we have through our relationship with BD. We view our primary competitors in this area to be Abbott Diagnostics, Bayer Diagnostics, and Roche Diagnostics. Abbott Laboratories, through its acquisition of Vysis, Inc., develops and markets clinical laboratory products targeting DNA chromosomal and genomic abnormalities for cancer and pre- and post-natal genetic disorders. Bayer Diagnostics and Roche Diagnostics operate in the immunoassay and tumor marker markets.

In addition to immunoassay based tests, we believe the staging, prognosis and prediction of outcomes will also be heavily influenced by the assessment of special stains utilizing immunohistochemical (IHC) and *in situ* hybridization techniques on tissue specimens. The primary companies currently competing in this area Dako Corporation and Ventana Medical Systems. Both companies specialize in automated IHC staining instrumentation and offer a wide range of validated IHC tumor markers.

We also have several competitors with competing technology in the molecular diagnostics field. TriPath Oncology faces a host of competition from companies such as Roche Diagnostics, Abbott Laboratories, EXACT Sciences Corporation, Correlogics Systems, Inc., Celera Diagnostics, and Bayer Diagnostics, all of which have announced active programs in this area. There can be no assurance that these or other competitors will not succeed in developing technologies and products that are more effective, easier to use or less expensive that those which we currently offer or are developing, or that would render our technology and products

obsolete. In addition, these or other competitors may succeed in obtaining FDA and other regulatory clearances and approvals of their products more rapidly than we do.

Government Regulation

The manufacture and sale of our medical diagnostic devices is subject to extensive governmental regulation in the United States and in other countries where we sell our products. In addition, our research and development activities in the United States are subject to various health and safety, employment and other laws and regulations.

United States FDA Approval

PrepStain and FocalPoint are regulated for cervical cytology applications in the United States as medical devices by the FDA under the Food, Drug and Cosmetic Act ("FDC Act") and require pre-market approval by the FDA prior to commercial distribution. In addition, certain modifications to the design, performance, manufacturing process or labeling of medical devices are subject to FDA review and approval before marketing. Pursuant to the FDC Act, the FDA regulates the clinical testing, manufacture, labeling, distribution, record keeping, reporting, sales, marketing, advertising and promotion of medical devices in the United States. Noncompliance with applicable requirements, including good clinical practice requirements and QSR requirements, can result in the refusal of the government to grant pre-market approval for devices, suspension or withdrawal of clearances or approvals, total or partial suspension of production, distribution, sales and marketing, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution of a company, its officers and employees.

Medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling and adherence to FDA-mandated quality system requirements, including QSR, and, in some cases, pre-market notification ("510(k)"). Class II devices are subject to general controls including, in most cases, pre-market notification, and to special controls (e.g., performance standards, patient registries and FDA guidelines). Generally, Class III devices are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices) and also include most devices that were not on the market before May 28, 1976, known as "new medical devices," and for which the FDA has not made a finding of "substantial equivalence" based on a pre-market notification. Class III devices usually require clinical testing that demonstrates the device is safe and effective, and must have FDA approval prior to marketing and distribution. The conduct of clinical studies is subject to FDA regulations, including requirements for institutional review board approval, informed consent, record keeping, and reporting. Our PrepStain and FocalPoint products, when intended for gynecological use, are regulated as Class III medical devices. In addition, the FDA has developed special rules for *in vitro* diagnostic devices, including restrictions on the sale and use of analyte specific reagents ("ASR's"). Products that we develop now and in the future may be subject to these and other applicable FDA regulations.

Device manufacturers are required to register their establishments and list their devices with the FDA and to provide periodic reports containing information on safety and effectiveness. The FDC Act requires that medical devices be manufactured in accordance with the FDA's QSR requirements. PrepStain and FocalPoint and any other products that we manufacture or distribute pursuant to an approved PMA application and any supplements, or pursuant to 510(k) clearances, or as ASR's, are and will be subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experience with the use of the device. We have established and maintain a system for tracking FocalPoint and PrepStain systems through the chain of distribution and conduct post-market surveillance. Product labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. We and our distributors may only promote products for their approved indications. If the FDA requires us to make modifications to our product labeling in the future, these changes may adversely affect our ability to market or sell PrepStain, FocalPoint or any of our other products.

To this end, we are subject to both routine and directed inspections by the FDA for compliance with regulations with respect to control activities, manufacturing, testing, distribution, storage, product labeling and promotions activities. We have been periodically inspected by the FDA at both our Burlington, North Carolina and Redmond, Washington facilities. In 2002, we were inspected at our Burlington facility with respect to our advertising and promotional activities, our manufacturing activities relative to a contemplated move of PrepMate manufacture from our Redmond to our Burlington facility and other aspects of our manufacturing operations. We have not as yet received a report from the FDA regarding the results of this inspection and cannot be assured that the FDA will not raise issues in their report on their inspection which would have an adverse effect on our selling and/or manufacturing activities.

In addition, the FDA's Medical Device Reporting regulations require medical device companies to provide information to the FDA whenever evidence reasonably suggests that a device may have caused or contributed to a death or serious injury. These regulations also apply if the device malfunctions and the device or a similar device sold by the company would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

If the FDA believes that we have not complied with the law, it can take one or more of the following actions:

- refuse to review or clear applications to market our products in the United States;
- refuse to allow us to enter into government supply contracts;
- withdraw approvals already granted;
- require that we notify users regarding newly found risks;
- request repair, refund or replacement of faulty devices;
- request corrective advertisements, recalls or temporary marketing suspension; or
- initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil or criminal penalties against us, our officers or employees.

These actions could seriously disrupt our operations for an indefinite period of time.

In June 1999, as a condition of the approval of the PrepStain system by the FDA, we were required to report results of a direct to vial study of PrepStain in our periodic post-approval reports. We worked in collaboration with the FDA to design the clinical study protocol and subsequently initiated the study following FDA approval of the protocol in August 2000. In October 2002, the FDA approved our request for early termination of this post-approval study based on the strength of the data collected. In its approval order, the FDA stated that it considered the conditions for approval to have been satisfied.

Environmental, Health, Safety and Other Regulations

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. Our manufacturing activities involve the use, storage, handling and disposal of hazardous materials and chemicals and, as a result, we are required to comply with regulations and standards of the Occupational Safety and Health Act and other safety and environmental laws. Although we believe that our activities currently comply with all applicable laws and regulations, the risk of accidental contamination or injury cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, which could have a material adverse effect on our business, financial condition and results of operations. Further, we can give 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.

Foreign Regulatory Approval

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 by 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. We have been advised by various parties, including consultants we engaged and foreign distributors, that no regulatory approvals for a device analogous to FDA approval of a PMA are currently required by any country where we currently sell PrepStain. Such approval requirements may be imposed in the future. In addition to regulatory approvals in the United States, the FocalPoint system is approved or accepted for primary screening and quality control re-screening in Japan, Canada, Australia, Germany, Belgium, the United Kingdom, Ireland, Switzerland, Denmark, Italy, Hong Kong, South Korea, and Taiwan. Placements of FocalPoint are also possible in The Netherlands, France, and many other countries where cervical screening is performed. In September 2001, we announced receipt of a Medical Device License in Canada to market both our PrepStain system and the PrepMate accessory. We intend to pursue additional product registrations in other foreign countries. We received an FDA permit to export PrepStain and FocalPoint to all foreign countries in which we are currently selling these products and where such a permit was required. There can be no assurance that we will meet the FDA's export requirements or receive additional 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.

Our products are subject to a variety of regulations in Europe, including the European Union. *In vitro* medical devices, including the FocalPoint system, must now comply with the EU's In-Vitro Diagnostic Medical Devices Directive ("IVDD"). In addition, Canadian regulations have similar, but distinct, requirements as those noted for the EU's IVDD which also became effective January 1, 2003. Efforts are underway to ensure our compliance with those requirements in order to continue to meet the customers' needs in the Canadian market segment as well. The Directive was published in the Official Journal of European Communities in December 1998. The EU member states were required to implement the Directive into national law by December 1999. A transition period, which began on from the date of publication of the Directive and ends December 2003, applies to all devices placed on the market in the EU. During this transition period, both Directive CE-marked and non-CE-marked devices may be placed on the market. In other words, companies may choose to follow either the CE mark or the national legislation, if any. If no such national legislation exists, the devices can be freely placed on the market. By the end of this transition period, our products must comply with the requirements of the Directive and member-state local language requirements. At such time, products not bearing the CE mark may not be commercially distributed in European Union member countries. In addition, member states may continue to restrict or prohibit the marketing of CE-marked devices pursuant to the safeguard clause of the Directive if the member state determines a particular device may compromise the health and/or safety of patients or users. We intend to comply with the Directive and other applicable regulations in accordance with the requirements of the countries in which we market and sell our products. Complying with the Directive will encompass, in no small part, providing our products with instructions for use in multiple languages.

Other European countries may enact national laws that would conform to the Directive. Member states of the EU and the European Economic Area may enact requirements in addition to those imposed by the Directive. Some European countries have established national regulations relating to *in vitro* diagnostic medical devices. EU directives and national laws impose requirements for electrical safety and electromagnetic compatibility that apply to the PrepStain system, PrepMate, and the FocalPoint system. We have performed the requisite testing procedures and related documentation to apply the European CE mark to the FocalPoint, PrepStain and PrepMate systems. We cannot guarantee that the FocalPoint system or any other product we may develop will receive any required regulatory clearance or approval on a timely basis, if at all.

Congress has directed the Department of Health and Human Services to issue regulations designed to improve the quality of biomedical analytic services, particularly the examination of Pap smears. These regulations require clinical laboratories to randomly re-screen at least 10% of the Pap smears classified on

initial manual screen as normal. This 10% must include normal cases selected from the laboratory's total caseload, and from patients or groups of patients that have a high probability of developing cervical cancer based on available patient information. Laboratories that purchase our PrepStain and FocalPoint products, or our ASR's, are subject to extensive regulation under the Clinical Laboratory Improvement Act of 1988, as amended (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 our PrepStain and FocalPoint products operate in a manner that will allow laboratories using our products to comply with CLIA requirements. However, there can be no assurance that interpretations of current CLIA regulations or future changes in CLIA regulations would not make compliance by the laboratory difficult or impossible and therefore have an adverse effect on sales of our products.

In addition, laboratories often must comply with state regulations, inspection, and licensing. In recent years, a few states, including New York and California, have adopted regulations that limit the number of slides that may be manually examined by a cytotechnologist within a given period of time. We cannot guarantee that states will not directly regulate FocalPoint in the future, nor can we predict the effect, if any, new regulations may have on our business or operations.

Product Liability

Commercial use of any of our products may expose us to product liability claims. We currently maintain general liability and product liability insurance coverage and believe that the amount of such coverage is adequate to meet our present needs. The medical device industry has experienced increasing difficulty in obtaining and maintaining reasonable product liability coverage, and substantial increases in insurance premium costs in many cases have rendered coverage economically impractical. To date, we have not experienced difficulty obtaining an amount of insurance coverage commensurate with our level of sales. As our sales expand, however, there can be no assurance that our existing product liability insurance will be adequate or that additional product liability insurance will be available to us at a reasonable cost, or that any product liability claim would not have a material adverse effect on our business, financial condition and results of operations.

Employees

As of December 31, 2002, we employed approximately 270 people on a full-time basis. We believe that relations with our employees are good. None of our employees are party to a collective bargaining agreement.

Item 1A. Executive Officers of the Registrant

Our current executive officers are as follows:

Name	Age	Position
Paul R. Sohmer, M.D.	54	President, Chief Executive Officer and Chairman of the Board
Stephen P. Hall	52	Senior Vice-President, Chief Financial Officer
Ray W. Swanson	47	Senior Vice-President, Commercial Operations
Johnny D. Powers, Ph.D.	41	Vice-President and General Manager, TriPath Oncology

Paul R. Sohmer, M.D. has served as our Chairman of the Board of Directors since November 2000, and as our President and Chief Executive Officer since June 2000. Prior to joining us, Dr. Sohmer served as the President and Chief Executive Officer of Neuromedical Systems, Inc. from 1997 through 1999. From 1996 until 1997, Dr. Sohmer served as President of a consulting firm which he founded. From 1993 to 1996, he served as President and Chief Executive Officer of Genetrix, Inc., a genetic services company based in Scottsdale, Arizona. From 1991 through 1993, Dr. Sohmer was the Corporate Vice-President of Professional Services and President of the Professional Services Organization for Nichols Institute, a clinical laboratory

company, where he was responsible for sales, marketing, information systems, logistics, and clinical studies. From 1985 until 1991, Dr. Sohmer served as the President and Chief Executive Officer of Pathology Institute in Berkeley, California, during which time he founded and served as Medical Director of the Chiron Reference Laboratory. Dr. Sohmer received a B.A. degree from Northwestern University and an M.D. from Chicago Medical School.

Stephen P. Hall has served as our Senior Vice-President and Chief Financial Officer since September 2001. Prior to joining us, Mr. Hall served as Chief Financial Officer and President of the Imaging and Power System Division of Colorado Medtech, Inc., a Colorado-based medical products and services company, from September 1999 until August 2001. From September 1993 to January 1999, he served as Chief Financial Officer for BioTechnica International, Inc., a publicly held agricultural products company, as well as privately held operating companies in the software development, wireless communication equipment and food processing machinery industries. Mr. Hall spent nine years in the commercial banking industry and four years with the accounting firm of Peat, Marwick, Mitchell & Co. He earned a A.B. degree from Harvard College and an MBA from the Stanford Graduate School of Business.

Ray W. Swanson has served as our Senior Vice-President of Commercial Operations since May 2001. Prior to joining us, he served as General Manager of e-Business for Dade Behring, one of the world's largest clinical diagnostics companies. Mr. Swanson held a number of senior management positions at Dade Behring and its predecessor companies since 1987. From 1997 to 1999, he was the general manager responsible for the introduction and market development of Dade's platelet function business. As President of Dade's Japanese subsidiary from 1994 to 1997, he was a member of the management team that purchased Baxter International's diagnostics businesses and created Dade International as a privately held, stand-alone company. Prior to 1987, he held positions with Johnson and Johnson, American Hospital Supply Corporation, Solvay (a global chemical and pharmaceutical company) and Washington University School of Medicine's Department of Anatomy and Neurobiology. Mr. Swanson has B.S. and M.S. degrees in zoology from Eastern Illinois University and an MBA from the University of Iowa.

Johnny D. Powers, Ph.D. has served as Vice-President and General Manager of TriPath Oncology since July 2002. From November 2001 to June 2002, Dr. Powers served as our Vice-President of Manufacturing Operations and Product Development in our Commercial Operations segment. Prior to joining us, he held a number of senior management positions at Ventana Medical Systems; most recently serving as Vice President and General Manager of Manufacturing Operations. Prior positions held at Ventana include Vice President and General Manager of Worldwide Strategic Marketing and Vice President of the Molecular Diagnostics Business Unit. Prior to 1996, Dr. Powers held various management positions at Organon Teknika Corporation, including Director of BioManufacturing and Manufacturing Technologies. Dr. Powers has a B.S. degree in Chemistry from Wake Forest University, a M.S. degree in Chemical Engineering from Clemson University, a Ph.D. in BioChemical Engineering from North Carolina State University and an MBA from Duke University.

Item 2. Properties

We currently lease a total of 43,000 square feet of space devoted to manufacturing, warehousing, administrative, research and development and engineering functions at 780 Plantation Drive, Burlington, North Carolina under a seven-year lease expiring in July 2005. The lease is renewable for five additional one-year terms. We lease approximately 72,000 square feet of office and manufacturing space in Redmond, Washington under operating leases expiring in December 2004. Of this space in Redmond, we sublease approximately 30,000 square feet as sub-lessor. We also currently lease approximately 10,000 square feet to serve as educational and corporate office space at 1111 Huffman Mill Road in Burlington, North Carolina under a three-year lease expiring in June 2004. This facility lease contained an option to expand the leased space by 4,500 square feet, which we exercised in June 2001. We also lease office space in Brussels, Belgium, under an operating lease expiring in August 2007. We lease approximately 22,000 square feet near the Research Triangle Park area, in Durham, North Carolina devoted primarily to the activities of TriPath Oncology. This lease has a seven-year term expiring in 2009. We believe that our facilities and other available office space are adequate for our current and future planned needs.

Item 3. Legal Proceedings

We are involved in various legal proceedings in the ordinary course of our business. In our opinion, we do not expect the ultimate outcome of the legal proceedings to have a material adverse effect on our financial condition or our results of operations.

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

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

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

Our Common Stock, $0.01 par value per share, is traded on the Nasdaq National Market under the symbol "TPTH". The following table sets forth, for the calendar periods indicated, the range of high and low bid and ask prices for our Common Stock on the Nasdaq National Market. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

	High	Low
Year ended December 30, 2001:		
First Quarter	$13.000	$5.000
Second Quarter	$12.490	$2.900
Third Quarter	$ 8.800	$3.030
Fourth Quarter	$ 8.190	$4.000
Year ended December 30, 2002:		
First Quarter	$ 8.270	$3.840
Second Quarter	$ 5.820	$3.360
Third Quarter	$ 4.380	$1.570
Fourth Quarter	$ 3.750	$1.500

On March 19, 2003, the last reported sales price of the Common Stock on the Nasdaq National Market was $3.86 per share. As of March 19, 2003, there were 37,537,940 shares of our Common Stock outstanding, which were held by approximately 355 Common Stockholders of record.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

Item 6. Selected Financial Data

The selected consolidated financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included elsewhere in this Form 10-K.

	Year ended December 31,				
	1998	1999	2000	2001	2002
	(in thousands, except per share data)				
Statement of Operations Data (3):					
Revenues	$ 16,849	$ 18,466	$ 32,652	$ 27,017	$ 37,485
Gross profit	7,155	8,098	16,529	13,921	22,563
Research and development (1)	15,969	12,258	9,629	9,259	11,247
Selling, general and administrative	25,408	17,724	23,867	27,346	29,798
Operating loss	(37,307)	(33,251)	(16,967)	(22,684)	(18,482)
Net loss	$(35,271)	$(32,557)	$(17,369)	$(21,680)	$(18,064)
Net loss per Share (basic and diluted) (2)	$ (1.46)	$ (1.17)	$ (0.60)	$ (0.61)	$ (0.48)
Weighted-average shares outstanding (3)	24,098	27,819	29,137	35,467	37,438

	December 31,				
	1998	1999	2000	2001	2002
	(in thousands)				
Balance Sheet Data (3):					
Cash, cash equivalents and short-term investments	$ 28,941	$ 13,962	$ 54,340	$ 55,976	$ 32,571
Working capital	32,553	17,338	62,316	62,898	38,837
Total assets	68,176	58,874	97,471	96,748	73,951
Long term obligations	2,051	1,117	3,760	5,001	220
Total stockholders' equity	$ 55,075	$ 47,025	$ 80,774	$ 77,291	$ 59,177

(1) Includes regulatory expenses.

(2) See Note 2 of Notes to our financial statements for information concerning the computation of net loss per share and shares used in computing net loss per share.

(3) The selected consolidated financial data has been restated to reflect the pooling transaction that occurred on September 30, 1999.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-K.

The discussion included in this section contains contain forward-looking statements based on current expectations of our management. Generally, those forward-looking statements use words like "expect," "believe," "continue," "anticipate," "estimate," "may," "will," "could," "opportunity," "future," "project," and similar expressions. Such statements are subject to risks and uncertainties that could cause actual results to differ from those projected. The forward-looking statements include statements about our: projected timetables for the pre-clinical and clinical development of, regulatory submissions and approvals for, and market introduction of our products and services; expected future revenues, operations and expenditures; and projected cash needs.

Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets in which we compete. These

forward-looking statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. We caution investors not to place undue reliance on the forward-looking statements contained in this report, which speak only as the date hereof. We undertake no obligation to update these statements to reflect events or circumstances occurring after the date of this report or to reflect the occurrence of unanticipated events, except as required by law.

Certain factors, among others, that could cause our actual results to differ materially from what is expressed in those forward looking statements include the following: we may be unable to successfully commercialize the diagnostic oncology products and services being developed by TriPath Oncology; our products may not receive regulatory approval when we expect, if at all; BD may change its business direction or priorities or default in its obligations to us; our products may not be accepted by the market to the extent we expect; we may be unable to establish and maintain licenses, strategic collaborations and distribution arrangements; implementation of the new CPT codes may not have the financial impact we expect; we may lack the financial resources necessary to further develop our marketing and sales capabilities domestically and internationally or to expand our manufacturing capability; we may be unable to comply with the extensive domestic and international governmental regulatory approval and review procedures to which the manufacture and sale of our products are subject, or lack the financial resources to bear the expense associated with such compliance; we may be unable to obtain and maintain adequate patent and other proprietary rights protection of our products and services; competition and technological change may make our products or potential products and technologies less attractive or obsolete; we may incur greater expenses than we expect with our clinical trials or they may take longer to complete than we expect; our promotional discounts, sales and marketing programs and strategies may not have their expected effect. These factors and others are discussed in more detail in Exhibit 99.1 "Factors Affecting Future Operating Results" to this Form 10-K, which is incorporated into this item by this reference.

Background

We create solutions that redefine the early detection and clinical management of cancer. Specifically, we develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We have developed and marketed an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We have created new opportunities and applications for our proprietary technology by applying recent advances in genomics, biology, and informatics to develop new molecular diagnostic and pharmacogenomic products and services for cancer of the cervix, breast, ovary, and colon.

We are organized into two operating units: (1) Commercial Operations, through which we manage the market introduction, sales, service, manufacturing and ongoing development of our products; and (2) TriPath Oncology, our wholly-owned subsidiary through which we manage the development of molecular diagnostic and pharmacogenomic products and services for cancer.

Commercial Operations

During 2002, we adopted the trademark "TriPath Care Technologies" to describe our commercial product offerings and to communicate the broad nature of our corporate vision and the value created by our growing product portfolio, including the "i^3 Series" and SlideWizard product lines.

Our "i^3 Series" product line for cervical cancer screening is the first integrated system for the collection, preparation, staining and computerized analysis of conventional Pap smears and liquid-based, thin-layer slide preparations. Our "i^3 Series" product line includes the following: the SurePath Test Pack, a proprietary, liquid-based cytology sample collection, preservation and transport system; the PrepStain Slide Processor, an automated slide preparation system that produces slides with a standardized, thin layer of stained cervical cells; the PrepMate, an accessory to the PrepStain designed to automate several steps in the preparation of

SurePath thin-layer slides; and the FocalPoint SlideProfiler, a computerized imaging system that uses proprietary technology to automatically screen SurePath or conventionally prepared Pap smear slides. The FocalPoint Slide Profiler with Location Guided Screening ("FocalPoint GS"), the next generation FocalPoint system, which has been introduced outside of the U.S. but has not yet been approved for use in the U.S., integrates our proprietary SlideWizard technology into the FocalPoint screening process and automates the microscopic analysis of cervical smears designated for further review by the FocalPoint slide profiler.

Our SlideWizard product line includes the Image Titer, an FDA cleared method for automating the measurement of antinuclear antibody, research applications for DNA, immunohistochemical quantification, cellular analysis, and expression quantification, a system for the transmission and interpretation of tissue specimens via remote telecommunications or "telepathology", and a software based storage and retrieval system for microscopic images.

We generate PrepStain revenue from either the sale, rental or lease of PrepStain systems and from the sale of the related SurePath and PrepStain test kits, comprised of proprietary reagents and other disposables. We generate FocalPoint related revenue from the direct sale of FocalPoint systems and from the placement of FocalPoint systems under fee-per-use contracts. Additionally, we generate revenue from service contracts on PrepStain and FocalPoint systems. We also generate revenue from either the sale or rental of our SlideWizard line of products and from service contracts on these products.

Our marketing strategy is focused on providing solutions that address the unmet needs of our three broad market stakeholders, i.e. clinical laboratories, clinician and third-party payors. We increased our marketing efforts during the first half of 2002 by directing resources toward various marketing-related initiatives designed to promote brand identification and awareness, increase market acceptance of our products and services and enhance product management. We have expanded our presence in the marketplace through increased advertising and promotion, company-sponsored seminars and trade shows, and peer selling activities. To further educate and reinforce the benefits of our products, we initiated a partnership with a third party physician/peer selling organization that continued into 2002. An important element of our marketing strategy is to achieve broad market acceptance of our integrated product consisting of our PrepStain thin-layer slides for cervical cancer screening by the FocalPoint system.

We are also leveraging our proprietary imaging technology to develop new collaborations to expand our commercial opportunities. In early 2003, we entered into an agreement with BMS to provide quantitative tissue based image analysis in support of their oncology therapeutics programs targeted at treating epithelial cancers including cancer of the cervix, breast and colon. We are utilizing our SlideWizard image analysis platform and proprietary software applications to provide a quantitative assessment of tumor marker expression levels from tissue samples provided by BMS for patients enrolled in a Phase I clinical trial. The data generated by our work will be used to evaluate patient response across varied dosing levels based on changes in tumor marker expression levels, both before and after treatment.

TriPath Oncology

Our TriPath Oncology business focuses on developing and commercializing molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancers of the cervix, breast, ovary, colon and prostate as part of the ongoing strategic alliance between Becton, Dickinson and Company (BD) and Millennium Pharmaceuticals, Inc. ("Millennium").

The goal of our molecular oncology program is to use new discoveries in genomics and proteomics research to develop and commercialize diagnostic and pharmacogenomic tests to improve the early detection and clinical management of cancer. Specifically, we have active programs in development designed to identify individuals with cancer at the earliest possible stage of the disease, provide individualized predictive and prognostic information, guide treatment selection for patients with cancer, and predict disease recurrence. The core products and services we are developing through our collaboration with BD will be based upon genomic and proteomic markers identified through discovery research conducted at Millennium under its existing research and development agreement with BD.

TriPath Oncology is not expected to generate any significant revenue until 2004. Consequently, for 2003, we expect that it will incur expenses in excess of revenues generated.

Strategy

In 2001, we implemented a strategy to: (1) build a "franchise" among academic centers of excellence; (2) target regional laboratories and health care provider networks where increased test volumes provide greater opportunity for repeat reagent sales; (3) stress reagent rental and in-house lease arrangements for placement of new PrepStain instruments; (4) leverage the ability of the FocalPoint to screen both conventional Pap Smears and SurePath thin-layer slides to drive reagent growth; (5) ensure attractive reimbursement for FocalPoint screening of SurePath thin-layer slides to complement currently paid premiums for FocalPoint screening of conventional Pap smears; and (6) create a strong international presence to complement our U.S. business.

In 2001, we implemented a series of management actions to advance our strategy. First, we expanded our sales and marketing team to approximately 110 sales and marketing professionals, including 40 who were contracted through Nelson Professional Services to provide detail selling to ordering physicians. Second, we revised our sales incentive programs to promote reagent sales. Third, we sought to build a "franchise" among academic centers of excellence and successfully added high profile, opinion leaders to our customer list. Fourth, we actively encouraged the presentation and publication in respected journals of independent investigators' experience with our SurePath and PrepStain products. As a result of this initiative, in excess of 40 papers were published or presented at international and national meetings regarding the performance of our products. Fifth, we directed our sales organization to target laboratories whose increased test volumes provide greater opportunity for repeat reagent sales. Sixth, we focused on the placement of new PrepStain instruments under reagent rental arrangements and in-house lease arrangements rather than IPO third party leasing programs, which historically had been the financing mechanism utilized by the majority of our customers. In addition, we received FDA approval for the PrepMate accessory to our PrepStain system in May 2001 and for FocalPoint screening of SurePath thin-layer slides in October 2001, and announced receipt of a Medical Device License in Canada to market both our PrepStain System and the PrepMate accessory in September 2001.

Our results in 2002 reflect our ongoing efforts to shift our product sales mix from capital equipment to higher margin reagent and disposable sales, to increase net realized revenue per test through improved pricing among new customers and reduced finance charges as we phase-out third party lease arrangements, to grow our base business through the addition of new customers, and to accelerate growth in reagent and disposable sales from pre-existing customers, and reflect the increased experience gained in selling our reagent and disposable products by our sales and marketing team as we continue to execute on the strategy that we implemented in 2001. As planned, we leveraged the ability of FocalPoint to screen both conventional Pap smears and SurePath thin-layer slides and the majority of domestic FocalPoint placements now screen both conventional Pap smear and SurePath thin-layer slides. In the fourth quarter of 2002, new CPT codes for automated screening of thin-layer slide preparations were established and published in the annual Current Procedural Terminology CPT 2003 of the American Medical Association. The 2003 Medicare Clinical Laboratory Fee Schedule became effective on January 1, 2003 and includes payment determinations for the automated screening of thin-layer slides that are at a premium to payment determinations for the manual screening of thin-layer slides, ensuring attractive reimbursement for FocalPoint screening of SurePath thin-layer slides. We increased our penetration of certain international target markets such as Canada, Germany, Switzerland, Belgium and the Netherlands as a complement to our U.S. business, as evidenced by our 131.4% growth in international sales of SurePath reagents and disposables. Finally, while our increased emphasis on reagent rental and in-house lease arrangements for placement of new PrepStain instruments has resulted in reduced revenue recorded from up front capital equipment sales associated with third party leasing programs, it has added significantly to our net realized revenue per test from the sale of reagents.

Results of Operations

Our reported operating results are affected by a number of critical accounting policies, which are described below in the section titled "Critical Accounting Polices."

Years ended December 31, 2002 and 2001

Revenues. Total revenues for the year ended December 31, 2002 were $37.5 million, a 38.7% increase from revenues of $27.0 million for 2001. Compared with 2001, the net increase in total revenues was primarily due to an increase in reagent sales of $13.8 million, or 126.6%, a net decrease in instrument sales of $3.7 million, or 36.5% and a net increase of $393,000 in other revenues, consisting primarily of fee-per-use sales, service on system placements, sales of non-instrument related SlideWizard products and various international consumable products, and freight.

In 2002, reagent sales increased $13.8 million worldwide compared with 2001. Domestic sales of our SurePath and PrepStain reagents increased $9.9 million, or 124.8%, while international sales increased $3.9 million, or 131.4%. As a percent of total revenues, reagent and disposable sales increased from 40.4% in 2001 to 66.0% in 2002. Net realized revenue per test in 2002 increased 17% from 2001, and we added in excess of 70 new SurePath consumable customers domestically during the year.

Sales of instruments decreased $3.7 million, or 36.5%, during 2002 compared to 2001. Sales of PrepStain instruments worldwide decreased by about $2.2 million, or 57.8%, during 2002, including a domestic decline of $2.8 million related to our shift away from sales of PrepStain instruments under our IPO program, partially offset by an increase of $652,000 internationally compared with 2001. We placed 76 PrepStain instruments domestically and 39 internationally during 2002. This compares with 97 domestic PrepStain units and 14 international units in 2001. There were no PrepStain instrument placements under third party financed IPO agreements in 2002. Worldwide sales of FocalPoint systems, including a partially offsetting increase in revenue from systems placed under rental agreements, decreased approximately $2.2 million during 2002. In 2002 we placed 11 domestic units and 16 international units. This compares with 21 domestic units in 2001, 15 of which were sold replacing fee-per-use contracts to one customer, and 10 international units. Revenues recorded for SlideWizard system sales increased $634,000 between 2002 and 2001. We placed 19 SlideWizard units in 2002 compared with 7 in 2001.

Other revenues, consisting primarily of fee-per-use sales, service on system placements, sales of non-instrument related SlideWizard products and various international consumable products, and freight, increased approximately $393,000 during 2002, mostly attributable to various international consumable product sales. FocalPoint fee-per-use revenues declined $1.1 million between 2002 and 2001, but we experienced an increase other consumable sales of $1.1 million, an increase in service revenue of $213,000, and an increase in freight and royalties of $323,000. We saw a slight decline in sales of non-system related SlideWizard revenues of $232,000.

Gross Margin. Gross margin improved significantly from 51.5% in 2001 to 60.2% in 2002. Gross margin increased as the result of growth in sales, the continuing shift from capital equipment to higher margin reagent and disposable sales, higher product prices to new accounts, the gradual phase out of third party leasing agreements, and the introduction of new efficiencies in our manufacturing operations.

Research and Development. Research and development expenses include salaries and benefits of scientific and engineering personnel, testing equipment, relevant consulting and professional services, components for prototypes and certain facility costs. Consolidated research and development expenses for 2002 were $8.5 million, a 16.9% increase from $7.3 million in 2001. Prior to 2001, our research and development expenses resulted entirely from research and development activities related to the i^3 Series and the Slide Wizard product lines. Incremental expenses related to the development of our molecular diagnostic markers, reagents, and assays were first incurred in the second half of 2001 immediately following the announcement of our agreements with BD and the creation of our TriPath Oncology operating segment. In 2001 and 2002, the increase in research and development costs related to the development of our molecular diagnostic markers, reagents and assays was partially off-set by a reduction in research expenses related to the PrepStain and

FocalPoint System as all research and development activities related to these products were limited to sustaining engineering and the development of specific customer driven enhancements. In addition, all new imaging research and product development activities unrelated to the development of instrument platforms for our molecular diagnostic products were eliminated. Since we initiated segment reporting in 2001, our TriPath Oncology segment incurred research and development expenses of $1.1 million and $ 6.4 million for 2001 and 2002, respectively, an increase of 491.3%. These expenditures reflected the redirection of all imaging research and development activities to the development of instrument platforms for our molecular diagnostic programs and the incremental expenses related to the development of our molecular diagnostic markers, reagents and assays. Our Commercial Operations segment incurred research and development expenses of $6.2 million and $2.1 million in 2001 and 2002 respectively, a decrease of 65.5%. These expenditures reflected reduced new research activity related to the i^3 Series product line and the transfer of expenses related to our imaging technology group to TriPath Oncology. In total, the expenses related to TriPath Oncology for 2002 include $2.5 million of amortization, against expense, of a deferred research and development credit arising out of the accounting for this transaction with BD. This compares with $1.0 million of amortization in 2001. We accounted for this transaction in accordance with Statement of Financial Accounting Standard No. 68, "Research and Development Arrangements". We began amortizing the credit in August 2001 and will continue the amortization at $206,600 per month against research and development expenses, fully amortizing in January 2004.

Regulatory. Regulatory expenses include salaries and benefits of regulatory and quality personnel, costs related to clinical studies and submissions to the FDA, and relevant consulting services. Regulatory expenses for the year ended December 31, 2002 were $2.7 million, representing a 38.3% increase from almost $2.0 million in 2001. This change was primarily attributable to the initiation and continuation of activities surrounding several clinical trials, particularly the FocalPoint GS and Alternative Collection Device trials, and to continued efforts surrounding the implementation of an updated quality management system. These expenses will likely increase in 2003 as the FocalPoint GS clinical trial continues, although some variability is possible depending on exact trial start dates and subsequent progress. From a segment perspective, regulatory expenses were $2.2 million in the Commercial Operations segment in 2002, compared with $2.0 million in 2001 while there were $519,000 of regulatory expenses incurred by the TriPath Oncology segment in 2002 versus none in 2001.

Sales and Marketing. Sales and marketing expenses include salaries and benefits of sales, marketing, sales support and service personnel, and their related expenses, as well as non-personnel-related expenses related to marketing our products. Sales and marketing expenses for the year ended December 31, 2002 were $19.9 million, including $986,000 of expenses related to TriPath Oncology, while our Commercial Operations incurred $18.9 million in this area. This represented a 6.2% increase overall from $18.7 million in 2001, during which $221,000 of sales and marketing expenses were attributable to TriPath Oncology and $18.5 million were incurred by our Commercial Operations segment. This year-over-year increase is modest and reflects our efforts begun in late 2000 to significantly expand our sales and marketing capabilities, including the addition of physician sales representatives in the third quarter of 2001 and the building of a marketing organization during the last half of 2001. During the second quarter of 2002, we terminated our agreement with Nelson Professional Sales and employed the majority of those physician sales representatives engaged under that arrangement. Additionally, we reorganized the sales force into six divisions, as opposed to three, to better divide the country into manageable territories. Overall, we expect that there will be some savings attributable to this reorganization and we anticipate that sales and marketing costs will range from $5.0 to $5.5 million per quarter during 2003.

General and Administrative. General and administrative expenses include salaries and benefits for administrative personnel, legal and other professional fees and certain facility costs. General and administrative expenses were $9.9 million in 2002 compared with $8.7 million in 2001. The net increase resulted from several sources. First, there was a net increase of approximately $620,000 during 2002 versus 2001 in amounts related to a contingent liability (see Note 5 to our Consolidated Financial Statements). Second, we recorded increases in personnel-related and corporate insurance costs between 2002 and 2001 of approximately $551,000. Third, overall general and administrative expenses included a provision for doubtful accounts of

$1.1 million in 2002 and $1.8 million in 2001, a decrease of approximately $760,000. Offsetting this decrease were reductions of certain other reserves, primarily warranties, in 2001, of approximately $797,000. Of the total general and administrative expenses, $4.1 million was recorded to our TriPath Oncology segment for the year ended December 31, 2002 with no expenses to the segment in 2001, while the Commercial Operations segment recorded $5.8 million and $8.7 million in 2002 and 2001, respectively.

Net Loss from Operations. Net loss from operations during 2002 was $18.1 million, a 16.7% improvement from $21.7 million in 2001. The improvement in net loss from operations largely reflects incremental gross profit on new sales of reagents. Total increases in gross profit contributed $8.6 million to the net improvement in net loss from operations in 2002 compared with 2001. The increase in gross margin was partially offset by an increase in operating expenses of $ 4.4 million or 12.1%, as described above.

Interest Income and Expense. Interest income for 2002 was $969,000, a 58.3% decrease from $2.3 million earned during 2001, primarily attributable to lower average cash balances in 2002 and to a continued depressed interest rate environment during 2002. The lower average cash, cash equivalent, and short-term investment balances reflected our net cash burn during 2002 which averaged almost $2.0 million monthly, though our cash burn rate during the fourth quarter of 2002 averaged $1.0 million per month. Interest expense for 2002 was $551,000 compared to $1.3 million during 2001. This decrease is due to reduced balances outstanding resulting from principal repayments under our debt facilities.

Years ended December 31, 2001 and 2000

Revenue. Revenues for the year ended December 31, 2001 were $27.0 million, a 17.3% decrease from revenues of $32.7 million for 2000. Sales related to the SurePath and PrepStain systems increased $5.3 million, or 56.2%, from 2000 to 2001. Consumable sales contributed largely to this increase, $5.2 million, or 90.3% from 2000 to 2001. Revenues related to the FocalPoint declined by $11.1 million, or 54.6%, for the same period. Other revenue, including sales of our SlideWizard products and revenue recorded under service agreements increased $99,000, or 3.2% between 2000 and 2001.

Our focus in 2001 on the placement of new PrepStain instruments under reagent rental arrangements and in-house lease arrangements rather than IPO third party leasing programs, which historically had been the financing mechanism utilized by the majority of our customers, as part of our strategic plan resulted in reduced revenue recorded from up front capital equipment sales associated with the IPO program in 2001.

The decline in FocalPoint related revenues from 2000 to 2001 represented a $9.1 million decline in fee-per-use revenues and a $2.0 million decline in instrument sales. We believe that this decline in FocalPoint related revenue was attributable to several factors. First, we believe that much of the decline resulted from the ongoing U.S. market shift toward liquid-based Pap testing, since the FocalPoint system was not FDA approved to screen SurePath thin-layer slides until the fourth quarter of 2001 and, therefore, could only be used for the screening of conventional Pap smears in the U.S. for most of the year. The decline in the number of tests performed on the FocalPoint corresponded with the general decline in conventional Pap smear testing in the U.S. in 2001. Subsequent to receiving FDA approval in October of 2001, we have leveraged the combined product to drive sales of reagents and disposables. Second, FocalPoint revenues declined due to completion of an arrangement entered into with Quest Diagnostics in 2000 subsequent to its signing a three-year exclusive agreement for liquid based thin-layer testing products with a competitor. Third, as described above, as we awaited FDA approval to screen SurePath slides with the FocalPoint, we shifted our sales focus to drive our higher margin reagent and disposable business.

Gross Margin. Gross margin improved slightly from 50.6% in 2000 to 51.5% in 2001. Contributing to the modest improvement in 2001 was increased sales of SurePath and PrepStain test kits for gynecological purposes.

Research and Development. Research and development expenses include salaries and benefits of scientific and engineering personnel, testing equipment, relevant consulting and professional services, components for prototypes and certain facility costs. Research and development expenses for 2001 were $7.3 million, a 17.1% decrease from $8.8 million in 2000. This decrease was primarily attributable to reduced professional

fees incurred in 2001. Included in research and development expenses in 2001 were $1.1 million of expenses related to our subsidiary, TriPath Oncology, which we established to carry out the research, development and commercialization efforts stemming from our agreement with BD. These expenses related to TriPath Oncology also reflect $1.0 million of amortization, against expense, of a deferred research and development credit arising out of the accounting for this transaction. We accounted for this transaction in accordance with Statement of Financial Accounting Standard No. 68, "Research and Development Arrangements". We began amortizing the credit in August 2001 and will continue the amortization over 30 months at $206,600 per month against research and development expenses.

Regulatory. Regulatory expenses include salaries and benefits of regulatory and quality personnel, costs related to clinical studies and submissions to the FDA, and relevant consulting services. Regulatory expenses for the year ended December 31, 2001 were $2.0 million, representing a 134.8% increase from $839,000 in 2000. This change was primarily attributable to the rebuilding and refocusing of our regulatory efforts, which began in the third quarter ended September 30, 2000, and to the regulatory efforts surrounding our FDA submissions, specifically those concerning FDA approval of the use of FocalPoint to process thin-layer slides prepared with PrepStain, and upcoming clinical studies.

Sales and Marketing. Sales and marketing expenses include salaries and benefits of sales, marketing, sales support and service personnel, and their related expenses, as well as non-personnel-related expenses related to marketing our products. Sales and marketing expenses for the year ended December 31, 2001 were $18.7 million, including $221,000 of expenses related to TriPath Oncology. This represented a 226.8% increase from $5.7 million in 2000. This increase is primarily due to our efforts to significantly expand our sales and marketing capabilities, including the addition of various employees and initiatives focused on product management and brand identification. We dramatically increased our sales and marketing staff to over 100 people by the end of 2001.

General and Administrative. General and administrative expenses include salaries and benefits for administrative personnel, legal and other professional fees and certain facility costs. General and administrative expenses, including the provision for doubtful accounts receivable of $1.8 million, for the year ended December 31, 2001 were $8.7 million, represents a 52.3% decrease from $18.1 million in 2000. This decrease is primarily due to one-time, non-cash compensation charges of $2.1 million related to repricing of stock options in 2000 and decreased legal costs, and related charges in 2001.

Net Loss from Operations. Net loss from operations during 2001 was $22.7 million, a 33.7% increase from $17.0 million in 2000. This increase is due to reduced gross profit, of $2.6 million, resulting from the 17.3% decrease in revenue coupled with increased operating expenses of $3.1 million, or 9.3%.

Interest Income and Expense. Interest income for 2001 was $2.3 million, an 84.8% increase from $1.3 million during 2000, primarily attributable to increased average cash balances during 2001 in spite of declining interest rates throughout 2001. The higher average cash balances resulted from a cash receipt of $25.0 million from BD for an investment in our Common Stock during the third quarter of 2001 and 43.0 million from Roche for an investment in our Common Stock in the fourth quarter of 2000. Interest expense for 2001 was $1.3 million compared to $1.7 million during 2000. This decrease is due to reduced balances outstanding resulting from principal repayments under our debt facilities.

Liquidity and Capital Resources

Since our formation, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of $224.5 million as of December 31, 2002. We have funded our operations primarily through the private placement and public sale of equity securities, debt facilities and limited product sales resulting in cumulative net proceeds of $216.6 million as of December 31, 2002. We had cash and cash equivalents of $32.6 million at December 31, 2002.

We funded our operations in 2002 from cash and cash equivalents on hand and revenues from our Commercial Operations segment. Cash used in our operations was $18.1 million in 2002, $19.0 million during

2001 and $8.2 million during 2000. Negative operating cash flow during 2002, 2001, and 2000 was caused primarily by operating losses.

Our capital expenditures were $2.2 million in 2002, $936,000 in 2001, and $217,000 during 2000 with expenditures primarily attributable to the purchase of machinery and equipment. We have no material commitments for future capital expenditures.

We had $2.5 million of short-term investments at December 31, 2001 that had matured by December 31, 2002 and were reinvested in accordance with our practice. The investments were part of managed portfolios of the excess cash we have to invest. Our short-term investments, when held, have a maturity of more than three months, but less than one year when purchased and are stated at cost. Our intent regarding these investments, when held, is to hold them to maturity.

We recorded $1.1 million to bad debt expense in 2002, compared with $1.8 million and $220,000 in 2001 and 2000, respectively. While we experienced a slowing of collections on several international accounts receivable during 2001 in large part attributable to an overall slowdown in the world economy, we actually experienced a strong year of collections of receivables during 2002. During 2002, cash collected on receivables was $37.9 million compared with $26.8 million in 2001. We have collected amounts on some of our older international accounts and continue to monitor them. We believe that, based on communications with these customers, additional amounts provided for possible bad debts and partial payments received during the year, that our accounts receivable reserve is adequate to cover any losses that may be realized. In addition, our revenue mix has shifted dramatically over the latter half of 2001 and throughout 2002 toward a higher concentration of higher margin consumable sales and away from a significant dependence on more sporadic sales of instrumentation. This has contributed to the improvement in our cash collections and days of sales outstanding we experienced throughout 2002. This not only has contributed to improved gross margins on our sales of our products, but it has further shortened the length of time our customers take to pay their invoices.

During 2000 and 2001, the declining interest rates in the U.S. impacted amounts earned on our invested funds. For the most part, the rate of decline in interest rates experienced over 2000 and 2001 slowed dramatically during 2002. Average yields on invested funds fell between 500 and 550 basis points, on average from 2000 through 2002. This is contrary to the fixed-rate nature of our borrowings and other term debt. If this interest rate environment continues, there will be a continued net negative impact on our cash relative to net interest income.

We recorded a short-term contingent liability of $2.4 million in accordance with the provisions of FASB SFAS No. 5, "Accounting for Contingencies," on the basis that the likelihood of a future event occurring was probable and reasonably estimable. That contingency related to our obligation to pay a third party, who received 180,000 shares of our common stock in January 2001 under a settlement agreement, an amount in cash equal to the difference between the average market price of our common stock on the ten trading days prior to January 8, 2003 and $16.00 per share. In accordance with the terms of this settlement agreement, we paid the third party a sum of $2.4 million in cash in January 2003 in full satisfaction of the outstanding liability.

Related Party Transaction

In connection with our collaboration with BD entered into in 2001, we lease several laboratories at BD's facility in Research Triangle Park, North Carolina. This arrangement substantially ended in July 2002 after TriPath Oncology occupied its own, newly equipped laboratory and office space in Research Triangle Park. However, we have maintained several small laboratories at the BD facility. Total rent paid to BD was $5,087 during 2001 and $130,195 during 2002.

Financing Arrangements

On February 8, 2000, we entered into a $7.0 million subordinated term loan with a syndicate of lenders to finance operations. We fully drew this facility during the first quarter of 2000. We have remaining amounts outstanding under this loan of approximately $758,000 at December 31, 2002. This loan will be fully repaid in

April 2003. At the present time, we have no plans to replace that loan with a similar facility after it is repaid (see Note 5 to the Consolidated Financial Statements).

During August 2002, we secured a lease line of credit from Bank of America. This line is secured by a letter of credit against our line of credit with Silicon Valley Bank (see Note 5 to the Consolidated Financial Statements and below). This lease line of credit, which carries three-year lease terms for items acquired under it, is being used to secure operating leases for assets, primarily equipment. As of December 31, 2002, there were assets of $1.0 million leased under this lease line.

In January 2003, we renewed our $5.0 million working capital facility with Silicon Valley Bank. This facility will expire on January 31, 2004. The outstanding balance is limited to an amount equal to 80% of eligible accounts receivable. The line bears interest at the bank's prime rate plus 1/2% and is collateralized by substantially all of our assets. The line of credit carries customary covenants, including the maintenance of a minimum modified quick ratio, minimum tangible net worth, and other requirements. We had no outstanding borrowings under this agreement at December 31, 2002, though the availability under the line of credit could provide additional funding if needed.

In March 2003 we obtained a commitment for a $2.5 million lease line of credit with GE Capital Corporation. This commitment, which carries three-year lease terms for items acquired under it, will be used to secure operating leases for assets, primarily equipment.

Except as described above and in Note 5 to the Consolidated Financial Statements, we have no other long-term debt commitments and no off-balance sheet financing vehicles.

Outlook

In the fourth quarter of 2002, the Commercial Operations segment achieved breakeven operations for the first time. We believe that the Commercial Operations segment will be profitable for the entire year of 2003. Regulatory expenses for 2003 will exhibit the greatest quarterly variability due to the timing and extent of anticipated clinical trials. Given this variability, the Commercial Operations segment may not exhibit profitability in all quarters of 2003. The excess cash flow generated from the Commercial Operations segment will be utilized, in part, to fund the operations of the TriPath Oncology segment.

The TriPath Oncology segment is not expected to generate any significant revenue until 2004 and, consequently, will continue to incur expenses in excess of revenues generated. We anticipate that during 2003, the TriPath Oncology segment will incur approximately $1.2 — $1.4 million of expenses per month up from $1.0 million per month in the fourth quarter of 2002.

Our total operating expenses in 2002 were $41.0 million. Our projected 2003 operating expenses should fall in the range of $42.0 to $46.0 million reflecting our intention to keep operating expenses in line with our expected top line growth and the increased expenditure levels at our TriPath Oncology segment discussed above.

We believe that we can manage our balance sheet to minimize cash requirements in 2003. We expect that our capital expenditures for 2003 will be under $1 million. We have a commitment for a $2.5 million lease line of credit which will be utilized for equipment placed under operating leases. The expenses associated with these leases are anticipated in our operating expense projections for 2003. We believe that our existing cash and anticipated additional debt and/or lease financing for internal use assets, rental placements of PrepStain and fee-per-use placements of FocalPoint, will be sufficient to enable us to meet our future cash obligations for at least the next 24 months.

While it is also possible that marketing and sales expenditures for the continued SurePath commercial rollout for gynecological uses in the United States, capital expenditures associated with placements of PrepStain units and FocalPoint fee-per-use instruments, and expenditures related to clinical trials, manufacturing, the TriPath Oncology segment and other administrative costs may increase, we anticipate that our future sales growth and the cost control measures we have implemented should preclude us from having to raise additional funds in the 2003 to 2004 time period. If, however, our existing resources prove insufficient to

satisfy our liquidity requirements, we may need to raise additional funds through bank facilities, the sale of additional equity or debt securities or other sources of capital. The sale of any equity or debt securities, if required, may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all, which would have a material adverse effect on our liquidity and capital resources, business, financial condition and results of operations.

Income Taxes and Tax Loss Carryforwards

We have not generated any taxable income to date and, therefore, have not paid any federal income taxes since inception. Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, we have established valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2002 and 2001,in each period to reflect these uncertainties.

At December 31, 2002, we had net tax losses of approximately $199.9 million that may be carried forward to offset future taxable income. In addition, we had research credits available for carryforward of $3.7 million. These amounts begin to expire in 2003. Utilization of net tax losses and any tax credit carryforwards are subject to complex treatment under the Internal Revenue Code of 1986, as amended (the "Code"). Pursuant to Section 382 of the Code, the change in ownership resulting from our initial public offering in September 1997 and any other future sale of stock may limit utilization of future losses in any one year. We believe that the sale of Common Stock in the offering did not create any immediate limitations on our utilization of net operating losses.

Critical Accounting Policies

The preparation of the Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles, 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. On an on-going basis, we evaluate our estimates, including those related to sales of our products, bad debts, inventories, investments, intangible assets, warranty obligations, and legal issues. Since not all of these accounting policies require management to make difficult, subjective or complex judgments or estimates, they are not all considered critical accounting policies. We believe the following critical accounting policies involve our more significant judgments and estimates used in the preparation of our consolidated financial statements. We reviewed our policies and determined that those policies identified below as our critical accounting policies remain our most critical accounting policies for the year ended December 31, 2002. We did not make any changes in those policies during the year.

Revenue Recognition

We record revenue from the sale, rental and/or lease of our systems and from the sale of related consumables. Additionally, we record revenue from service contracts on our systems. In the case of system sales to end users, revenue recognition on system sales occurs at the time the instrument is installed and accepted at the customer site. In the case of instrument sales to distributors, revenue recognition on system sales occurs based upon the contract governing the transaction, typically at the time the instrument is shipped from our facility. This was the predominant vehicle for international instrument sales in 2002. If, however, we sell an instrument directly to an international end user, we record the revenue upon installation and acceptance of the instrument, as we do in the U.S. For system rentals, systems are placed at the customer's site free of charge and the customer is obligated either to purchase reagent kits for a fixed term, or are charged fees based on monthly minimum, or actual, usage. Under these transactions, there is no capital equipment revenue recognized. We also offer leasing alternatives. Under these transactions, we may, or may not, recognize revenue on system hardware depending on the particular details of the lease. We consider the accounting policies surrounding revenue recognition to be critical primarily due to the distributed nature of our sales network. We sell through a direct sales force in the U.S., and the issues related to revenue recognition are essentially clear-cut domestically. Abroad, however, we sell both through various distributor networks and directly to end user customers. This requires us to examine each sales transaction to ensure that we properly

and consistently apply the appropriate accounting guidance covering revenue recognition. Sales of consumable products are recorded at shipment.

Allowance for Doubtful Accounts and Notes Receivable

We continuously monitor payments from our customers and maintain an allowance for doubtful accounts and notes receivable for estimated losses resulting from the inability of our customers to make required payments. When we evaluate the adequacy of our allowance for doubtful accounts and notes, we take into account various factors including our accounts and notes receivable aging, customer credit-worthiness, historical bad debts and current economic trends. We are closely monitoring several delinquent accounts with past due balances outstanding, and will continue to do so, to determine the need, if any, to further increase our allowance for doubtful accounts and notes receivable. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. In assessing the adequacy of our allowance for doubtful accounts and notes, management meets weekly with individuals responsible for collecting outstanding accounts and notes receivable balances. Management reviews the work undertaken during the course of the week by those responsible for collections and guides activities for the following week's actions intended toward collections of outstanding accounts and notes receivable. Accounts are discussed specifically, and to the extent they show potential for aging beyond acceptable limits, adjustments to our allowance for doubtful accounts and notes are discussed and made. At December 31, 2002 and 2001, our accounts receivable balance, net of allowance for doubtful accounts and notes receivable of $3.6 million and $3.3 million, respectively, was $9.4 million and $9.6 million.

Inventory

Inventory is stated at the lower of cost or net realizable value on a first-in, first-out basis If we determine that net realizable value is less than cost, then we write down the related inventory to market value. We review net realizable value of inventory in detail on an on-going basis, with consideration given to deterioration, obsolescence, and other factors. If actual market conditions are less favorable than those projected by management, and our estimates prove to be inaccurate, additional write-downs or adjustments to recognize additional cost of goods for overstated inventory may be required. A significant portion, almost 67%, of our inventory is related to our FocalPoint product. Of that FocalPoint inventory, much of it is classified as raw material, or component parts. A significant reason we consider accounting policies around inventory as critical is due to the relatively slower moving nature of the FocalPoint instrument. We continue to monitor actual demand for the product and the economic environment into which we will be selling it during 2003. After reviewing these factors, we do not believe that it is necessary to record any further adjustments to inventory. At December 31, 2002 and 2001, our total inventory balance, net of reserves for obsolescence of $1.8 million and $2.3 million, respectively was $11.0 million and $10.7 million.

Valuation of long-lived and intangible assets

We review the value of our long-lived assets, including patents and other intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. If we determine that the carrying value of intangibles and long-lived assets may not be recoverable based upon one or more indicators of impairment, the asset is written down to its estimated fair value based on a discounted cash flow basis. There was no impairment loss recorded in 2002. During 2001, however, we recognized $430,000 of such a loss for the placement of certain Customer-Use Assets free of charge at a customer under a two-year contract. We consider long-lived and intangible assets to warrant the designation of critical for several reasons. One is tied to the issue mentioned in "Inventory" above, the relatively slower moving nature of the FocalPoint instrument. One of our ways of selling FocalPoint instruments is under usage based arrangements ("fee-per-use"). We have a number of FocalPoint instruments recorded on the balance sheet in the account "Customer use assets". We continue to monitor actual demand for the product and the economic environment into which we will be selling it during 2003. Should these instruments be returned prior to the term of the agreements, there could be possible impairment issues surrounding these assets. The second reason we consider this a critical

accounting area is due to the nature of our reliance on our intellectual property. Should competitors develop and market products that would render ours redundant or obsolete, then we would face impairment issues surrounding our intangible assets as well. After reviewing the relevant factors affecting our assets in these categories, we do not believe that it is necessary to record any further adjustments to our long-lived and intangible assets.

Recently Issued Accounting Standards

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"). SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our results of operations or financial position.

In April 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) ("Issue 94-3"). SFAS 146 addresses the accounting and reporting for costs associated with exit or disposal activities resulting from entities increasingly engaging in exit and disposal activities where certain costs associated with those activities were recognized as liabilities at a plan (commitment) date under Issue 94-3 but did not meet the definition of a liability in FASB Concepts Statement No. 6, "Elements of Financial Statements." The standard is effective for us beginning January 1, 2003. The adoption of SFAS 146 would have had no material impact on our results of operations or financial position for the twelve months ending, nor as of, December 31, 2002.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123" ("SFAS 148"). 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 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. The standard is presently effective for us, and we have adopted it accordingly. We adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. There was no impact on our basic financial statements resulting from its adoption. Rather, the effects of the statement are reflected in our Notes to Consolidated Financial Statements by elevating the prominence of certain disclosures regarding our stock-based compensation plans.

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others (an interpretation of FAS No. 5, 57 and 107 and rescission of FAS Interpretation No. 34)" ("FIN 45"), which modifies the accounting and enhances the disclosure of certain types of guarantees. FIN 45 requires that upon issuance of certain guarantees, the guarantor must recognize a liability for the fair value of the obligation it assumes under the guarantee. The provisions of FIN 45 for the initial recognition and measurement are to be applied to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of annual periods that end after December 15, 2002. The adoption of FIN 45 had no material impact on our results of operations or financial position for the twelve months ending, nor as of, December 31, 2002.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51" ("FIN 46"), which requires a new approach in determining if a reporting entity should consolidate certain legal entities, including partnerships, limited liability companies, or trusts, among others, collectively defined as variable interest entities, or VIEs. A legal entity is considered a

VIE if it does not have sufficient equity at risk to finance its own activities without relying on financial support from other parties. If the legal entity is a VIE, then the reporting entity that is the primary beneficiary must consolidate it. Even if a reporting entity is not obligated to consolidate a VIE, then certain disclosures must be made about the VIE if the reporting entity has a significant variable interest. Certain transition disclosures are required for all financial statements issued after January 31, 2003. The on-going disclosure and consolidation requirements are effective for all interim financial periods beginning after June 15, 2003. The adoption of FIN 46 had no material impact on our results of operations or financial position for the twelve months ending, nor as of, December 31, 2002.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Our primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. Our financial results and cash flows are subject to fluctuation due to changes in interest rates, primarily from our investment of available cash balances in highly rated institutions. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. See *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* under *Liquidity and Capital Resources* for further discussion of the impact of interest rates on our financial results. We operate in several foreign countries and are subject to fluctuations in foreign currencies to a minor extent. We have no foreign exchange contracts, option contracts, or other foreign hedging arrangements. However, the impact of fluctuations in foreign currencies on our financial results has not been material and are unlikely to have a material adverse effect on our business, financial condition or results of operations in the future.

Item 8. Financial Statements and Supplementary Data

The information required by this item may be found on pages F-1 through F-23 of this Form 10-K.

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

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

PART III

Item 10. Directors and Executive Officers of the Registrant

The response to this item is contained in part under the caption "Executive Officers of the Registrant" in Part I, Item 1A hereof and the remainder is incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors" and "Section 16(a) Beneficial Reporting Compliance" in our Proxy Statement relating to our Annual Meeting of Stockholders scheduled for May 22, 2003 (the "Proxy Statement").

Item 11. Executive Compensation

The response to this item is incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors," "Director Compensation," "Executive Compensation" and "Compensation Committee Interlocks, Insider Participation and Certain Transactions" in the Proxy Statement.

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

The response to this item, other than the information related to Securities Authorized for Issuance Under Equity Compensation Plans, which appears below, is incorporated in part herein by reference from the discussion responsive thereto under the captions "Share Ownership" in the Proxy Statement.

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of December 31, 2002:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:	3,367,510(1)	$6.00	2,364,066(2)
Equity compensation plans not approved by security holders:	—	—	—
Total:	**3,367,510(1)**	**$6.00**	**2,364,066(2)**

(1) This table excludes an aggregate of 399,473 shares issuable upon exercise of outstanding options assumed by the Company in connection with the acquisition of NeoPath, Inc. in September 1999. The weighted-average exercise price of the excluded options is $13.02.

(2) Includes 924,701 shares issuable under the Company's 2000 Employee Stock Purchase Plan, all of which are issuable in connection with the current offering period which ends on June 30, 2003, assuming maximum participation of all employees to the extent permitted.

Item 13. Certain Relationships and Related Transactions

The response to this item is incorporated herein by reference from the discussion responsive thereto under the caption "Compensation Committee Interlocks, Insider Participation and Certain Transactions" in the Proxy Statement. See also Note 9 to the Consolidated Financial Statements included herewith.

Item 14. Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures within 90 days of the filing date of this annual report. Based on their evaluation, our principal executive officer and principal financial officer concluded that these controls and procedures are effective in timely alerting them to material information required to be disclosed by us in the reports that we file with the SEC. There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

PART IV

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

(a) 1. *Financial Statements*

The consolidated financial statements are listed under Part II, Item 8 of this report.

2. *Financial Statement Schedule*

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

3. *Exhibits*

The exhibits are listed under Part IV, Item 15(c) of this report.

(b) *Reports on Form 8-K*

On August 14, 2002, TriPath Imaging, Inc. filed a current report on Form 8-K with the SEC announcing that we filed our quarterly report on Form 10-Q for the quarter ended June 30, 2002 with the Securities & Exchange Commission and attached as correspondence to that Form 10-Q the certifications of our Chief Executive Officer and our Chief Financial Officer, as required by 18 U.S.C. Section 1350.

(c) *Exhibits*

3.1	Restated Certificate of Incorporation of the Company. Filed as Exhibit 3.1 to our Form 10-Q for the quarter ended June 30, 2002 (File No. 0-22885) and incorporated herein by reference.
3.2	Amended and Restated By-laws of the Company. Filed as Exhibit 3.2 to our Form 10-Q for the quarter ended June 30, 2002 (File No. 0-22885) and incorporated herein by reference.
4.1	Specimen of Common Stock Certificate. Filed as Exhibit 4.1 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference.
10.1*	Amended and Restated 1996 Equity Incentive Plan (including forms of incentive stock option certificate and nonstatutory stock option certificate). Filed as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference.
10.2*	1997 Director Stock Option Plan (including form of director non-statutory stock option certificate). Filed as Exhibit 10.2 to our Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference.
10.3*	Form of Indemnification Agreement between the Company and its Directors and Executive Officers. Filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference.
10.4	Lease Agreement dated as of July 28, 1997 by and between Carolina Hosiery Mills, Inc. and the Company. Filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-30227) and incorporated herein by reference.
10.5	Lease Agreement dated June 12, 1998 by and between Carolina Hosiery Mills, Inc. and AutoCyte, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-22885) and incorporated herein by reference.
10.6	Amendment dated March 2, 1999 to Lease Agreement dated July 28, 1997 by and between Carolina Hosiery Mills, Inc. and AutoCyte, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended March 31, 1999 (File No. 0-22885) and incorporated herein by reference.
10.7	Intellectual Property Purchase Agreement dated as of April 24, 1999 by and between NeoPath, Inc. and AutoCyte, Inc. Filed as Exhibit 10.21 to the Amendment No. 2 to the Company's S-1 (File No. 333-82121) and incorporated herein by reference.

10.8 Loan and Security Agreement dated as of January 19, 2000 by and between MMC/GATX Partnership No. I, Transamerica Business Credit Corporation and TriPath Imaging, Inc. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended March 31, 2000 (File No. 0-22885) and incorporated herein by reference.

10.9 Loan and Security Agreement dated as of January 31, 2000 (the "Loan and Security Agreement") by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended March 31, 2000 (File No. 0-22885) and incorporated herein by reference.

10.10 Securities Purchase Agreement, dated September 26, 2000, by and among TriPath Imaging, Inc., Roche International Ltd. and Certain Stockholders of TriPath Imaging. Filed as Exhibit 99.2 to the Company's Form 8-K as filed with the commission on October 24, 2000 (File No. 0-232885) and incorporated herein by reference.

10.11 Securities Purchase Agreement dated as of July 31, 2001 by and between the Company and Becton, Dickinson and Company. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference.

10.12 Securities Purchase Agreement dated as of July 31, 2001 by and among the Company, Millennium Pharmaceuticals, Inc. and mHoldings Trust. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference.

10.13 License and Intellectual Property Access Agreement dated as of July 31, 2001 by and between the Company and Becton, Dickinson and Company. Filed as Exhibit 10.3 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference.

10.14 Development and License Agreement dated as of July 31, 2001 by and among the Company, Becton, Dickinson and Company and TriPath Oncology, Inc. Filed as Exhibit 10.4 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference.

10.15 Sublicense Agreement dated as of July 31, 2001 by and among the Company, Becton, Dickinson and Company and TriPath Oncology, Inc. Filed as Exhibit 10.5 to the Company's Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22885) and incorporated herein by reference.

10.16 Lease Agreement between NeoPath, Inc. and Teachers Insurance & Annuity Association dated October 1, 1994 (the "Lease Agreement") and all amendments thereto. Filed as Exhibit 10.25 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.17 Sublease Agreement by and between NeoPath, Inc. and Antioch Bible Church dated as of August 31, 1999. Filed as Exhibit 10.26 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.18 Assignment of the Lease Agreement from NeoPath, Inc. to AutoCyte, Inc. dated September 28, 1999. Filed as Exhibit 10.27 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.19† OEM Supply Agreement dated November 1, 2001 by and between Tecan Schweiz AG and the Company. Filed as Exhibit 10.28 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.20 Amendment dated December 1, 2001 to Lease Agreement dated June 12, 1998 by and between Carolina Hosiery Mills, Inc. and TriPath Imaging, Inc. Filed as Exhibit 10.29 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.21 Second Loan Modification Agreement to the Loan and Security Agreement effective as of January 31, 2002 by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed as Exhibit 10.30 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.22 Lease Agreement dated as of February 6, 2002 by and between TBC Place Partners II, LLC and TriPath Oncology, Inc. Filed as Exhibit 10.31 to the Company's Form 10-K for the year ended December 31, 2001 (File No. 0-22885) and incorporated herein by reference.

10.23 Third Loan Modification Agreement to the Loan and Security Agreement effective as of June 17, 2002 by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed herewith.

10.24 Lease Agreement dated as of July 1, 2002 by and between Banc of America Leasing & Capital, LLC and TriPath Imaging, Inc. Filed herewith.

10.25 Fourth Loan Modification Agreement to the Loan and Security Agreement effective as of January 31, 2003 by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed herewith.

21.1 List of all subsidiaries of the Company. Filed herewith.

23.1 Consent of Ernst & Young LLP, independent auditors to the Company. Filed herewith.

99.1 Factors Affecting Future Operating Results. Filed herewith.

99.2 Certification pursuant to 18 U.S.C. Section 1350. Filed herewith.

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* Indicates a management contract or compensatory plan.

† Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to both Rule 406 of the Securities Act of 1933, as amended, and Rule 24b-2 of the Securities Exchange Act of 1934, as amended, as applicable. Omitted information is identified with asterisks in the appropriate places in the agreement.

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, in the City of Burlington, State of North Carolina, on March 24, 2003.

TRIPATH IMAGING, INC.

By: /s/ PAUL R. SOHMER
Paul R. Sohmer, M.D.
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on this 24th day of March, 2003.

Signature	Title
/s/ PAUL R. SOHMER Paul R. Sohmer, M. D.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ STEPHEN P. HALL Stephen P. Hall	Senior Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ THOMAS A. BONFIGLIO Thomas A. Bonfiglio, M.D.	Director
/s/ HAYWOOD D. COCHRANE, JR. Haywood D. Cochrane, Jr.	Director
/s/ ROBERT E. CURRY Robert E. Curry, Ph.D.	Director
/s/ ROBERT L. SULLIVAN Robert L. Sullivan	Director

Certification Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934

I, Paul R. Sohmer, certify that:

1. I have reviewed this annual report on Form 10-K of TriPath Imaging, Inc.;

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

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

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

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

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

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

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

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/ PAUL R. SOHMER, M.D.

Paul R. Sohmer, M.D.
Chief Executive Officer

Certification Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934

I, Stephen P. Hall , certify that:

1. I have reviewed this annual report on Form 10-K of TriPath Imaging, Inc.;

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

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

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

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

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

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

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

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/ STEPHEN P. HALL

Stephen P. Hall
Chief Financial Officer

TRIPATH IMAGING, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

TRIPATH IMAGING, INC.

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders
TriPath Imaging, Inc.

We have audited the accompanying consolidated balance sheets of TriPath Imaging, Inc. and subsidiaries as of December 31, 2002 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, 2002. 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 TriPath Imaging, Inc. and subsidiaries at December 31, 2002 and 2001, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Raleigh, North Carolina
January 31, 2003

TRIPATH IMAGING, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,571	$ 53,477
Short-term investments	—	2,499
Accounts receivable, less allowance of $3,554 and $3,285 at December 31, 2002 and 2001, respectively	9,370	9,581
Inventory, less reserves for obsolescence of $1,828 and $2,312 at December 31, 2002 and 2001, respectively	10,973	10,718
Other current assets	477	1,079
Total current assets	53,391	77,354
Customer use assets, net	6,357	6,089
Property and equipment, net	4,063	2,362
Other assets	930	916
Patents, less accumulated amortization of $2,419 and $1,752 at December 31, 2002 and 2001, respectively	7,126	7,793
Other intangible assets, less accumulated amortization of $916 and $766 at December 31, 2002 and 2001, respectively	2,084	2,234
Total assets	$ 73,951	$ 96,748
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,341	$ 4,411
Accrued expenses	5,436	4,116
Deferred revenue and customer deposits	1,103	730
Deferred research and development funding	2,479	2,479
Current portion of long-term debt	785	2,720
Other current liabilities	2,410	—
Total current liabilities	14,554	14,456
Long-term debt, less current portion	13	790
Other long-term liabilities	207	4,211
Stockholders' equity:		
Preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.01 par value; 98,000,000 shares authorized; 37,454,234 and 37,304,738 shares issued and outstanding at December 31, 2002 and 2001, respectively	375	373
Additional paid-in capital	283,396	283,395
Deferred compensation	(78)	—
Accumulated deficit	(224,482)	(206,418)
Accumulated other comprehensive loss	(34)	(59)
Total stockholders' equity	59,177	77,291
Total liabilities and stockholders' equity	$ 73,951	$ 96,748

See accompanying notes

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2002	2001	2000
Revenues	$ 37,485	$ 27,017	$ 32,652
Cost of revenues	14,922	13,096	16,123
Gross profit	22,563	13,921	16,529
Operating expenses:			
Research and development	8,522	7,289	8,790
Regulatory	2,725	1,970	839
Sales and marketing	19,850	18,685	5,718
General and administrative	9,948	8,661	18,149
	41,045	36,605	33,496
Operating loss	(18,482)	(22,684)	(16,967)
Interest income	969	2,321	1,256
Interest expense, including amortization of non-cash debt issuance costs under term loan agreement	(551)	(1,317)	(1,658)
Net loss	$(18,064)	$(21,680)	$(17,369)
Net loss per common share (basic and diluted)	$ (0.48)	$ (0.61)	$ (0.60)
Weighted-average common shares outstanding	37,438	35,467	29,137

See accompanying notes

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share and per share amounts)

	Common Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income(Loss)	Total Stockholders' Equity
Balance at January 1, 2000	$281	$214,892	$(779)	$(167,369)	$ —	$ 47,025
Exercise of options and warrants	8	1,543	—	—	—	1,551
Private issuance of common stock and warrants	50	42,950	—	—	—	43,000
Issuance of warrants as consideration under term loan agreement	—	1,725	—	—	—	1,725
Re-pricing of warrants issued as consideration under term loan agreement	—	420	—	—	—	420
Re-pricing of stock options	—	2,134	—	—	—	2,134
Issuance of stock based compensation	2	1,618	—	—	—	1,620
Adjustment to deferred compensation	—	(22)	22	—	—	—
Amortization of deferred compensation	—	—	668	—	—	668
Net loss	—	—	—	(17,369)	—	(17,369)
Comprehensive loss						(17,369)
Balance at December 31, 2000	341	265,260	(89)	(184,738)	—	80,774
Exercise of options and warrants	3	934	—	—	—	937
Private issuance of common stock	29	17,777	—	—	—	17,806
Re-pricing of warrants issued as consideration under term loan agreement	—	(576)	—	—	—	(576)
Amortization of deferred compensation	—	—	89	—	—	89
Foreign currency translation	—	—	—	—	(59)	(59)
Net loss	—	—	—	(21,680)	—	(21,680)
Comprehensive loss						(21,739)
Balance at December 31, 2001	373	283,395	—	(206,418)	(59)	77,291
Exercise of options and warrants	2	234	—	—	—	236
Re-pricing of warrants issued as consideration under term loan agreement	—	(350)	—	—	—	(350)
Deferred compensation related to grant of stock options	—	152	(152)	—	—	—
Adjustment to deferred compensation	—	(35)	35	—	—	—
Amortization of deferred compensation	—	—	39	—	—	39
Foreign currency translation	—	—	—	—	25	25
Net loss	—	—	—	(18,064)	—	(18,064)
Comprehensive loss						(18,039)
Balance at December 31, 2002	$375	$283,396	$ (78)	$(224,482)	$(34)	$ 59,177

See accompanying notes.

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2002	2001	2000
OPERATING ACTIVITIES			
Net loss	$(18,064)	$(21,680)	$(17,369)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,044	3,071	5,868
Amortization of intangible assets	817	817	817
Amortization of deferred compensation	39	89	668
Non-cash equity compensation	—	—	2,134
Issuance of stock based compensation	—	—	1,620
Amortization of deferred research and development	(2,479)	(1,033)	—
Amortization of non-cash debt issuance costs	225	487	507
(Gain) loss on disposal of fixed assets	(3)	(9)	1
Other non-cash items	885	695	1,260
Changes in operating assets and liabilities:			
Accounts receivable	233	2,005	(6,160)
Inventory	(3,005)	(2,135)	1,328
Other current assets	603	(218)	(25)
Other long-term assets	(28)	(809)	187
Accounts payable and accrued expenses	(767)	100	1,444
Deferred revenue and customer deposits	373	(427)	(520)
Net cash used in operating activities	(18,127)	(19,047)	(8,240)
INVESTING ACTIVITIES			
Purchases of property and equipment	(2,251)	(936)	(217)
Disposals of property and equipment	5	9	—
Sales (Purchases) of short-term investments	2,499	(2,499)	—
Additions to intellectual property	—	—	(18)
Other	—	107	—
Net cash provided by (used in) investing activities	253	(3,319)	(235)
FINANCING ACTIVITIES			
Net proceeds from issuance of common stock and warrants	—	17,806	43,000
Proceeds from exercise of stock options and warrants	236	937	1,551
Other	—	(41)	(79)
Proceeds from research and development agreement	—	6,198	—
Proceeds from long-term debt	—	—	8,500
Payments on long-term debt	(3,286)	(3,292)	(4,119)
Net cash (used in) provided by financing activities	(3,050)	21,608	48,853
Effect of exchange rate changes on cash	18	(105)	—
Net (decrease) increase in cash and cash equivalents	(20,906)	(863)	40,378
Cash and cash equivalents at beginning of year	53,477	54,340	13,962
Cash and cash equivalents at end of year	$ 32,571	$ 53,477	$ 54,340
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for interest	$ 326	$ 830	$ 1,151
NONCASH INVESTING AND FINANCING ACTIVITIES			
Issuance of warrants as consideration under term loan agreement and subsequent re-pricing	$ (350)	$ (576)	$ 2,145

See accompanying notes.

1. Background

We create solutions that redefine the early detection and clinical management of cancer. Specifically, we develop, manufacture, market, and sell proprietary products for cancer detection, diagnosis, staging, and treatment selection. We are using our proprietary technologies, and know-how to create an array of products designed to improve the clinical management of cancer. We were formed in September 1999 through the merger of AutoCyte, Inc. and NeoPath, Inc. and acquisition of the technology and intellectual property of Neuromedical Systems, Inc. We were created to leverage the complementary nature of the products, technologies, and intellectual property developed by our predecessor companies, all of whom were early pioneers in the application of computerized image processing and analysis to detect the often subtle cellular abnormalities associated with cancer and its precursors. To date, we have developed and market an integrated solution for cervical cancer screening and other products that deliver image management, data handling, and prognostic tools for cell diagnosis, cytopathology and histopathology. We have created new opportunities and applications for our proprietary technology by applying recent advances in genomics, biology, and informatics to develop new molecular tests for cancer of the cervix, breast, ovary, and colon.

We are organized into two operating units:

- Commercial Operations, through which we manage the market introduction, sales, service, manufacturing and ongoing development of our products; and
- TriPath Oncology, our wholly-owned subsidiary through which we manage the development of molecular diagnostic and pharmacogenomic tests for cancer.

Our TriPath Oncology segment was formed on July 31, 2001 when we entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium"). In connection with our agreements with BD, we established TriPath Oncology, Inc. ("TriPath Oncology"), our wholly-owned subsidiary, to manage the activities for this development and commercialization effort. TriPath Oncology will develop molecular diagnostic and pharmacogenomic tests for malignant melanoma and cancer of the prostate, breast, ovary, cervix and colon. These products will be based upon the genomic discovery research, conducted at Millennium, under its existing research and development agreement with BD. TriPath Oncology and BD will configure validated markers provided by Millennium, under its agreement with BD, into commercial diagnostic and pharmacogenomic products and services. Commercial responsibilities for resulting products will be shared between BD and TriPath Oncology.

Information on our operations by segment and geographic area is included in Note 8.

On March 25, 1999, we entered into a purchase and sale agreement to acquire the intellectual property estate of Neuromedical Systems, Inc. ("NSI"), a developer of interactive, neural net technology for the computer screening of conventional Pap smears. The purchase was completed in May, 1999. This intellectual property estate is held by AutoCyte North Carolina, LLC, our wholly-owned subsidiary.

Revenues from sales of products have not generated sufficient cash to fully support our operations. We have incurred substantial losses since inception. We have funded our operations primarily through the private placement and public sale of equity securities, debt and lease financing, and product sales. We continue to be subject to certain risks and uncertainties common to early stage medical device companies including the uncertainty of availability of additional financing, extensive government regulation, uncertainty of market acceptance of our products, limited manufacturing, marketing and sales experience and uncertainty of future profitability.

2. Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include our accounts and those of our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Reclassifications

Certain amounts for the prior years, specifically those attributable to our TriPath Oncology segment (see note 8) and to our accounting for health care costs, have been reclassified to more accurately reflect cost of revenues, research and development and general and administrative expenses and to conform to the 2002 presentation. These reclassifications had no effect on previously reported net earnings or financial position.

Revenue Recognition

We record revenue from the sale, rental and/or lease of our systems and from the sale of related consumables. Additionally, we record revenue from service contracts on our systems. In the case of system sales to end users, revenue recognition occurs at the time the instrument is installed and accepted at the customer site. In the case of instrument sales to distributors, revenue recognition occurs based upon the contract governing the transaction, typically at the time the instrument is shipped from our facility. This was the predominant vehicle for international instrument sales for all years presented. If, however, we sell an instrument directly to an international end user, we record the revenue upon installation and acceptance of the instrument, as we do in the U.S. For system rentals, systems are placed at the customer's site free of charge and the customer is obligated either to purchase reagent kits for a fixed term, or are charged fees based on a monthly minimum, or actual, usage. Under these transactions, there is no capital equipment revenue recognized. We also offer leasing alternatives. Under these transactions, we may, or may not, recognize revenue on system hardware depending on the particular details of the lease. Sales of consumable products are recorded on shipment. Revenue and costs related to shipping products to customers are included in both revenues and cost of revenues, respectively.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

Short-term Investments

Short-term investments had a maturity of more than three months, but less than one year when purchased and were stated at cost, which approximated market value.

Inventory

Inventory is stated at the lower of cost or net realizable value (first-in first-out basis). Net realizable value of inventory is reviewed in detail on an on-going basis, with consideration given to deterioration, obsolescence, and other factors.

Customer-Use Assets

PrepStain and FocalPoint systems manufactured for rental or fee-per-use placements are carried in inventory until the systems are shipped, at which time they are reclassified to customer-use assets (non-current assets). Reclassifications of $2,473, $418, and $2,143 occurred between customer-use assets, property and equipment and inventory during 2002, 2001, and 2000, respectively. Customer-use assets are depreciated on a straight-line basis over an estimated useful life of four years. Depreciation expense of customer-use assets amounted to $1,516, $1,850, and $4,184 during 2002, 2001, and 2000, respectively.

Property and Equipment

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives (three to seven years) of the individual assets. Depreciation expense of property and equipment amounted to $1,251, $943, and $1,488 during 2002, 2001, and 2000, respectively.

Patents

Patents consist of patents and core technology acquired from NSI. Such assets are amortized using the straight-line method over estimated useful lives ranging from 14 to 20 years (See also "Other Intangible Assets" below).

Other Intangible Assets

As of January 1, 2002, we adopted Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"), which was issued in July 2001. SFAS 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. We completed our evaluation of goodwill under SFAS 142 and the net book value of $2,234 relates to specifically identifiable intangible assets, namely acquired rights to certain intellectual property surrounding our pathology workstation products and our location-guided screening technology. These intangible assets will be amortized over the next 14 years. Included in 2002, 2001 and 2000 is $150 of amortization attributable to the specifically identifiable intangible assets.

Asset Impairment

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), which superseded SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("SFAS 121"). SFAS 144 removes goodwill from its scope, thus eliminating the SFAS 121 requirement to allocate goodwill to long-lived assets to be tested for impairment. The accounting for goodwill is now subject to SFAS No. 141, "Business Combinations" ("SFAS 141") and SFAS 142. The provisions of SFAS 144 are effective for fiscal years beginning after December 15, 2001, and have been adopted by the Company, as required, in fiscal year 2002. There has been no significant impact from the adoption of SFAS 144 on our financial statements.

We periodically review the value of our long-lived assets to determine if an impairment has occurred. In accordance with SFAS No. 144, if this review indicates that the assets will not be recoverable, as determined

based on an analysis of undiscounted cash flows over the remaining amortization period, we would reduce the carrying value of our long-lived assets accordingly. During 2001, we recognized $430 of such a loss for the placement of certain Customer-Use Assets free of charge at a customer under a two-year contract. There were no such losses recognized in 2000 or 2002.

Deferred Revenue

Deferred revenue consists of up-front cash receipts related to FocalPoint and PrepStain service and equipment contracts, the revenue portion subject to contingencies under capitalized leases and a worldwide exclusive international distributor agreement for our ImageTiter product. Pursuant to the terms of an agreement related to the

ImageTiter product, we received a $1,000 non-refundable payment for the agreement, services to be performed, and as a payment for future product shipments. Revenue related to the worldwide exclusive international distributor agreement is recognized ratably over four years. The balance remaining to be recognized as revenue amounted to $51 and $151 at December 31, 2001 and 2000, respectively. There was no balance at December 31, 2002. The deferred revenue subject to contingencies under capitalized leases will be recognized once those contingencies have been met. Revenue related to service and equipment contracts is recognized as earned.

Income Taxes

We account for income taxes using the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes". Under the liability method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities. We have not generated any taxable income to date and, therefore, have not paid any federal income taxes since our inception. Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, we have established valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2002 and 2001, in each period to reflect these uncertainties (see note 6).

Research and Development Costs

Research and development costs are charged to operations as incurred.

Stock Based Compensation

We account for stock options issued to employees in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Under APB 25, no compensation expense is recognized for stock or stock options issued with an exercise price equivalent to the fair value of our Common Stock. For stock options granted at exercise prices below the deemed fair value, we record deferred compensation expense for the difference between the exercise price of the shares and the deemed fair value. Any resulting deferred compensation expense is amortized ratably over the vesting period of the individual options.

Effective July 1, 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" ("FIN 44"). FIN 44 provides guidance on issues regarding the application of APB 25. We adopted the guidance provided by FIN 44 with effect from July 1, 2000. We recorded non-cash equity compensation expense of $2,134 for the 2000 year in accordance with the requirements of APB 25 and FIN44. There were no such expenses recognized in 2001 or 2002.

In October 1995, the FASB issued SFAS No. 123, "Accounting for Stock Based Compensation" ("SFAS 123"). For companies that continue to account for stock based compensation arrangements under

(In thousands, except share and per share amounts)

APB 25, SFAS 123 requires disclosure of the pro forma effect on net income (loss) and earnings (loss) per share as if the fair value based method prescribed by SFAS 123 had been applied.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123" ("SFAS 148"). 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 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 (see below). The standard is effective for us beginning with these financial statements and we have adopted its provisions herein.

Had compensation cost for our stock options been determined based on the fair value at the date of grant consistent with the provisions of SFAS 123, with respect to our Equity Incentive Plans and our Employee Stock Purchase Plan (see Note 7), our pro forma net loss and net loss per share would have been as follows:

	Year Ended December 31,		
	2002	2001	2000
Net loss:			
As reporte	$(18,064)	$(21,680)	$(17,369)
Pro forma	$(20,994)	$(24,889)	$(20,061)
Net loss per common share (basic & diluted):			
As reported	$ (0.48)	$ (0.61)	$ (0.60)
Pro forma	$ (0.56)	$ (0.70)	$ (0.69)

Net Loss Per Common Share

Per share information is based upon the weighted-average number of shares of common stock outstanding during the period. We incurred losses during all periods presented. As a result, options and warrants were not used to compute diluted loss per share since the effect would be anti-dilutive. Accordingly, there is no difference between basic and diluted loss per share in the periods presented.

Advertising Expense

The cost of advertising is expensed as incurred. Advertising and marketing expense, including trade show expense, amounted to $1,044, $1,333, and $314 during 2002, 2001, and 2000, respectively.

Foreign Currency Translation

The financial statements of foreign subsidiaries and branches have been translated into U.S. dollars in accordance with SFAS No. 52, "Foreign Currency Translation." All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year. The gains and losses resulting from the changes in exchange rates were immaterial in 2000. In 2001 and 2002 the loss has been reported in other comprehensive loss. The effect on the consolidated statements of operations of transaction gains and losses is insignificant for all years presented.

Comprehensive Loss

We adopted SFAS No. 130, "Reporting Comprehensive Income" ("SFAS 130") effective January 1, 1998. SFAS 130 requires that we display an amount representing comprehensive income (loss) for the year in a financial statement, which is displayed with the same prominence as other financial statements. We elected to present this information in the Statement of Stockholders' Equity.

Concentration of Credit Risk

Our principal financial instruments subject to potential concentration of credit risk are cash, cash equivalents, short-term investments, accounts receivable and notes receivable. We invest our funds in highly rated institutions, and limits our investment in any individual debtor. We provide an allowance for doubtful accounts equal to the estimated losses to be incurred in the collection of accounts and notes receivable.

Derivative Financial Instruments

As of January 1, 2001, we adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), which was issued in June 1998, and its amendments, SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133" and SFAS No. 138, "Accounting for Derivative Instruments and Certain Hedging Activities" issued in June 1999 and June 2000, respectively (collectively referred to as SFAS 133). SFAS 133 establishes a comprehensive and consistent standard for the recognition and measurement of derivatives and hedging activities. The application of the new rules has not had a significant impact on our consolidated financial position or results from operations.

Recently Issued Accounting Standards

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"). SFAS 143 requires an entity to record a liability for an obligation associated with the retirement of an asset at the time that the liability is incurred by capitalizing the cost as part of the carrying value of the related asset and depreciating it over the remaining useful life of that asset. The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our results of operations or financial position.

In April 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) ("Issue 94-3"). SFAS 146 addresses the accounting and reporting for costs associated with exit or disposal activities resulting from entities increasingly engaging in exit and disposal activities where certain costs associated with those activities were recognized as liabilities at a plan (commitment) date under Issue 94-3 but did not meet the definition of a liability in FASB Concepts Statement No. 6, "Elements of Financial Statements." The standard is effective for us beginning January 1, 2003. We do not expect the adoption of SFAS 146 to have a material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others (an interpretation of FAS No. 5, 57 and 107 and rescission of FAS Interpretation No. 34)" ("FIN 45"), which modifies the accounting and enhances the disclosure of certain types of guarantees. FIN 45 requires that upon issuance of certain guarantees, the guarantor must recognize a liability for the fair value of the obligation it assumes under

the guarantee. The provisions of FIN 45 for the initial recognition and measurement are to be applied to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of annual periods that end after December 15, 2002. The adoption of FIN 45 had no material impact on our results of operations or financial position for the twelve months ending, nor as of, December 31, 2002.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51" ("FIN 46"), which requires a new approach in determining if a reporting entity should consolidate certain legal entities, including partnerships, limited liability companies, or trusts, among others, collectively defined as variable interest entities, or VIEs. A legal entity is considered a VIE if it does not have sufficient equity at risk to finance its own activities without relying on financial support from other parties. If the legal entity is a VIE, then the reporting entity that is the primary beneficiary must consolidate it. Even if a reporting entity is not obligated to consolidate a VIE, then certain disclosures must be made about the VIE if the reporting entity has a significant variable interest. Certain transition disclosures are required for all financial statements issued after January 31, 2003. The on-going disclosure and consolidation requirements are effective for all interim financial periods beginning after June 15, 2003. The adoption of FIN 46 had no material impact on our results of operations or financial position for the twelve months ending, nor as of, December 31, 2002.

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(In thousands, except share and per share amounts)

3. Balance Sheet Information

Select detailed balance sheet information is as follows:

	December 31, 2002	December 31, 2001
Accounts receivable		
Trade accounts receivable	$ 6,219	$ 7,462
Current portion of notes receivable	2,818	1,781
Other accounts receivable	333	338
	$ 9,370	$ 9,581
Inventory		
Raw materials	$ 6,934	$ 7,442
Work-in-process	629	275
Finished goods	3,410	3,001
	$10,973	$10,718
Customer-use assets		
Customer-use systems	$11,525	$11,976
Accumulated depreciation	(5,168)	(5,887)
	$ 6,357	$ 6,089
Property and equipment		
Machinery and equipment	$ 3,313	$ 2,708
Demonstration equipment	756	782
Furniture, fixtures and improvements	1,695	1,521
Leasehold improvements	1,318	1,318
Vehicles	24	48
Computer equipment and software	9,157	7,000
Total property and equipment	16,263	13,377
Accumulated depreciation	(12,200)	(11,015)
	$ 4,063	$ 2,362
Other Assets		
Notes receivable, less current portion	$ 838	$ 852
Deposits and other assets	92	64
	$ 930	$ 916
Accrued expenses		
Accrued payroll and related benefits	$ 3,177	$ 1,544
Accrued warranty costs	440	514
Other accrued expenses	1,819	2,058
	$ 5,436	$ 4,116

(In thousands, except share and per share amounts)

4. Allowance for Doubtful Accounts

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

	December 31,		
	2002	2001	2000
Balance, beginning of year	$3,285	$1,475	$1,347
Amounts charged to expense	1,050	1,810	220
Amounts written off	(781)	-	(92)
Balance, end of year	$3,554	$3,285	$1,475

5. Long-Term Obligations and Commitments

Subordinated Term Loan

On February 8, 2000, we entered into a $7,000 subordinated term loan with a syndicate of lenders to finance operations. We fully drew this facility during the first quarter of 2000. As of December 31, 2002 and 2001, respectively, the balance outstanding was $758 and $3,600, including a current portion of $758 at December 31, 2002 and $2,800 at December 31, 2001 and a long-term portion of $758 at December 31, 2001. The loan, which is secured by substantially all of our assets, including intellectual property, accrues interest at the three-year U.S. Treasury note rate plus 8% (14.6% and 14.5% at December 31, 2002 and 2001, respectively). Accrued interest was due monthly for the first six months of each draw, at which time the outstanding principal balance became payable over thirty-month terms. In connection with this term loan, we issued to the lenders warrants to purchase 223,253 shares of our common stock. Using a Black-Scholes pricing model, the warrants were valued upon issuance at $675, which represented non-cash debt issuance costs. These warrants, which expire in 2007, were recorded as additional paid-in capital, and the resulting debt issuance costs are being amortized on a straight-line basis to interest expense over the three-year term of the loan. These warrants have a weighted-average exercise price of $4.70 and were exercisable upon issuance. The loan will be fully repaid during the second quarter of 2003.

Note Payable to Finance Company

In December 1998, we entered into an agreement with an equipment financing company to provide us with a $5,000 line of credit to finance certain of our equipment purchases. We had outstanding borrowings of $3 and $467 under the agreement at December 31, 2002 and 2001, respectively. The agreement has a loan term of 48 months, and the loan is secured by a security interest in the financed equipment. Interest is calculated based on the four-year Treasury Bill Weekly Average rate plus 6.121%.

Working Capital Facility

In February 2002, we renewed a $5,000 working capital facility with a bank. The outstanding balance is limited to an amount equal to 80% of eligible accounts receivable. The line commitment expires on January 31, 2003 and management intends to renew the line for an additional year until January 31, 2004. The line bears interest at the bank's prime rate plus 1/2% and is collateralized by substantially all of our assets. The line of credit carries customary covenants, including the maintenance of a minimum modified quick ratio and other requirements. We had no outstanding borrowings under this agreement at December 31, 2002.

At December 31, 2002, maturities of the outstanding debt are as follows:

2003	$785
2004	13
	$798

(In thousands, except share and per share amounts)

The fair value of our long-term debt, which approximates the carrying value, is estimated using discounted cash flow analysis based on our current incremental borrowing rates for similar type borrowing arrangements.

Leases and Lease Lines of Credit

During August 2002, we obtained a $1,500 lease line of credit ("lease line") from Bank of America. This lease line is secured by a $1,500 letter of credit against our line of credit with Silicon Valley Bank discussed above. This lease line carries three-year lease terms for items acquired under it and financing charges based on three-year constant Treasury Maturities. The lease line will be used as an alternative source of capital to secure operating leases for assets, primarily equipment. As of December 31, 2002, there were $1,041 of assets leased under this lease line.

We also lease our office and manufacturing facilities and certain other office equipment under operating leases, with various renewal options, expiring at various times through 2010.

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

2003	$2,024
2004	2,031
2005	775
2006	273
2007	280
Thereafter	452
	$5,835

Rent expense amounted to $1,656, $1,220 and $1,341 during 2002, 2001 and 2000, respectively.

Other Liabilities

We have recorded a short-term contingent liability of $2,410 in accordance with the provisions of SFAS No. 5, "Accounting for Contingencies," on the basis that the likelihood of a future event occurring is probable and reasonably estimable. This contingency related to our obligation to pay a third party, who received 180,000 shares of our common stock in January 2001 under a settlement agreement, an amount in cash equal to the difference between the market price of our common stock on a specified date in January 2003 and a predetermined target price. An amount of $2,410, attributable to this contingent liability, was paid to the third party in settlement of this liability in January 2003.

We entered into a series of agreements with Becton, Dickinson and Company ("BD") on July 31, 2001, to develop and commercialize molecular diagnostics and pharmacogenomic tests for cancer as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc. ("Millennium"). We have accounted for the transaction in accordance with the provisions of SFAS No. 68, "Research and Development Arrangements." In connection with the transaction, we recorded $6,198 in deferred research and development ("R&D") funding, which will be amortized against such expenses over thirty months on a straight line basis. During 2002 and 2001, $2,479 and $1,033, respectively, of amortization was recorded against R&D expenses. Included in current and other long-term liabilities at December 31, 2002 are the unamortized balances of $2,479 and $207, respectively.

(In thousands, except share and per share amounts)

6. Income Taxes

At December 31, 2002, we had net tax loss carryforwards of approximately $199,866, which begin to expire in 2003 for federal income tax purposes. We also have approximately $3,746 in research and development carryforwards that begin to expire in 2003. Due to the prior issuance and sale of shares of preferred stock, the prior merger and changes in ownership, we have incurred "ownership changes" pursuant to applicable regulations in effect under the Internal Revenue Code of 1986, as amended.

Our use of losses incurred through the date of these ownership changes may limit the ultimate utilization of these losses. To the extent that any single-year loss is not utilized to the full amount of the limitation, such unused loss is carried over to subsequent years until the earlier of its utilization or the expiration of the relevant carryforward period.

Approximately $5,535 of the net tax loss carryforward is attributed to the deduction for stock options, the tax effect of which will be credited to equity when recognized.

Deferred income taxes reflect the net tax effects of temporary differences between the tax basis of assets and liabilities and the corresponding financial statement amounts. Significant components of our deferred income tax assets (liabilities) are as follows:

	December 31,	
	2002	2001
Net tax loss carryforwards	$ 69,953	$ 63,515
Research and development credits	3,746	3,417
Accrued vacation	159	107
Accrued warranty costs	154	180
Allowance for doubtful accounts	1,244	1,150
Charitable contribution carryforwards	15	15
Deferred research and development	940	1,808
Intangible assets, net of amortization	2,528	1,527
Inventory	1,515	2,751
Other	1,470	713
Property and equipment	(859)	368
Valuation allowance	(80,865)	(75,551)
	$ —	$ —

Due to the uncertainty of our ability to generate taxable income to realize our deferred tax assets, a valuation allowance has been established for financial reporting purposes equal to the amount of the net deferred tax assets. Our valuation allowance was $80,865 and $75,551 at December 31, 2002 and 2001, respectively.

7. Stockholders' Equity

Preferred Stock

Pursuant to our amended and restated Certificate of Incorporation, the Board of Directors has the authority, without further vote or action by the stockholders, to issue up to 1,000,000 shares of Preferred Stock in one or more series and to fix the relative rights, preferences, privileges, qualifications, limitations and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences, sinking fund terms and the number of shares

(In thousands, except share and per share amounts)

constituting any series or the designation of such series, any or all of which may be greater than the rights of Common Stock. At December 31, 2002 there were no shares of Preferred Stock outstanding.

Private Equity Transaction

On July 31, 2001, we completed a private placement of securities under Regulation D of the Securities Act with BD pursuant to which BD acquired 2,500,000 shares of our common stock for $10.00 per share. We accounted for a portion of these proceeds in accordance with the provisions of FASB SFAS No. 68, "Research and Development Arrangements" and recorded $6,198 thereof as deferred research and development funding, which will be amortized against such expenses over thirty months on a straight line basis. The transaction with BD provided us with an additional $25,000 in cash. In a separate agreement, Millennium and we entered into a research license for our evaluation of certain patents in the area of colon cancer. In consideration of this agreement, we issued to Millennium 400,000 shares of our common stock. We also paid $1,000 in connection with other aspects of the transaction.

On November 14, 2000, we completed a $43,000 private equity transaction with a subsidiary of Hoffmann-La Roche ("Roche") in terms of which Roche acquired 5,000,000 shares of our common stock for $8.00 per share. Additionally, Roche simultaneously acquired, for an aggregate purchase price of $3,000, warrants to purchase an additional 5,000,000 shares at strike prices ranging from $10.00 to $15.00 per share. The proceeds from the sale of these warrants were recorded as additional paid-in capital. If not exercised, these warrants will expire in November 2003.

Equity Incentive Plans

We have stock option plans (the "Plans") under which incentive and non-statutory stock options, stock appreciation rights and restricted stock may be granted to our employees, directors or consultants. Generally, options and restricted stock grants vest ratably over a 48-month term. Stock options expire ten years from the date of grant.

A summary of activity under the Plans is as follows:

	Options Outstanding	
	Number of Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2000	2,821,042	$6.34
Options granted	1,081,700	9.13
Options exercised	(279,061)	3.36
Options canceled/expired	(136,219)	8.62
Outstanding at December 31, 2001	3,487,462	7.26
Options granted	897,850	4.78
Options exercised	(127,354)	1.19
Options canceled/expired	(490,975)	8.23
Outstanding at December 31, 2002	3,766,983	$6.74

(In thousands, except share and per share amounts)

	Options Outstanding			Options Exercisable	
Price Range	Number Outstanding At December 31, 2001	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Exercisable At December 31, 2001	Weighted-Average Exercise Price
$0.20-0.20	76,021	3.9	$ 0.20	76,021	$ 0.20
1.52-2.28	61,264	8.5	2.01	11,568	1.85
2.35-3.25	14,291	6.9	2.92	9,830	2.94
3.67-5.50	1,998,930	7.3	4.72	1,193,395	4.84
5.52-8.25	780,085	6.9	6.36	480,653	6.28
8.30-10.94	590,070	7.6	10.82	324,396	10.81
14.24-20.09	206,017	4.1	16.41	206,017	16.41
21.51-29.89	40,305	3.9	26.44	40,305	26.44
$0.20-$29.89	3,766,983	7.0	$ 6.74	2,342,185	$ 7.18

Employee Stock Purchase Plan

In 2002, we introduced an employee stock purchase plan with 1,000,000 shares of common stock for authorized issuance. The plan permits substantially all employees to purchase a limited number of shares of the Corporation's stock at 85% of market value. We issue shares to employees semi-annually in June and December of each year. A summary of shares issued is as follows:

June	24,142
December	51,158

SFAS 123

We have adopted the disclosure-only provisions of SFAS 123. In accordance with SFAS 123, the fair value of each grant under its plans was determined by using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2002	2001	2000
Risk-free interest rate	3.86%	4.59%	6.37%
Expected dividend yield	0.00%	0.00%	0.00%
Expected lives	48 months	48 months	48 months
Expected volatility	1.02	1.02	0.90
Weighted-average fair value of grants	$ 4.78	$ 9.13	$ 4.51

Warrants

On February 9, 1999, we completed a $14,500 private equity transaction. In connection with the financing, we issued to a related party five-year warrants to purchase 79,030 shares of common stock at an exercise price of $7.45 per share.

On February 8, 2000, we closed a $7,000 subordinated term loan with a syndicate of lenders to finance operations (see Note 5). We issued warrants to the lenders to purchase 223,253 shares of common stock at a weighted-average exercise price of $4.70 per share. The warrants were exercisable upon issuance and expire in 2007. None of these warrants had been exercised as of December 31, 2002.

(In thousands, except share and per share amounts)

In connection with our November 14, 2000 private equity transaction with Roche, we issued to Roche, for an aggregate purchase price of $3,000, warrants to purchase 5 million shares of common stock at a weighted exercise price of $11.50 per share. The warrants were immediately exercisable and expire in November 2003. None of these warrants had been exercised by December 31, 2002.

As of December 31, 2002, there were 5,302,283 warrants outstanding with a weighted-average exercise price of $11.15. These warrants expire at various dates through 2007.

Common Stock Reserved for Future Issuance

At December 31, 2002, we have reserved authorized shares of Common Stock for future issuance as follows:

	December 31, 2002
Outstanding stock options	3,766,983
Possible future issuance under equity incentive plans	1,439,365
Possible future issuance under Employee Stock Purchase Plan	924,700
Common stock warrants	5,302,283
Total shares reserved	11,433,331

Deferred Compensation

In accordance with APB 25, for stock options and restricted stock grants granted at exercise prices below the deemed fair value, we record deferred compensation expense for the difference between the exercise price of the shares and the deemed fair value. The amounts are amortized over the vesting period of the individual options, generally 48 months. Amortization of deferred compensation amounted to $39, $89 and $668 during 2002, 2001 and 2000, respectively. We adjusted the deferred compensation amount by $35 and $22 to reflect the cancellation, accelerated vesting and non-forfeiture of options granted to terminated employees in 2002 and 2000, respectively.

8. Operations by Industry Segment and Geographic Area

Description of Products and Services by Segment

We currently operate in two business segments: Commercial Operations and TriPath Oncology (see Note 1).

Measurement of Segment Profit or Loss and Segment Assets

We evaluate performance and allocate resources based on operating profit or loss. The accounting policies of the reportable segments are the same as those described under the summary of significant accounting policies (see Note 2 above). Inter-segment transfers are recorded at cost.

Factors Management Used to Identify the Company's Reportable Segments

Our reportable segments are business units that offer different products and services. The reportable segments are each managed separately because they develop and commercialize distinct products. The segments operate as separate entities.

(In thousands, except share and per share amounts)

Results by Segment

Results for 2000 as reflected in the Consolidated Statements of Operations relate to the Commercial Operations segment only. The results, by segment, for 2002 and 2001 follow:

	Commercial Operations	2002 TriPath Oncology	Total
Revenues	$37,485	$ —	$ 37,485
Cost of revenues	14,922	—	14,922
Gross profit	22,563	—	22,563
Operating expenses:			
Research and development	2,142	6,380	8,522
Regulatory	2,206	519	2,725
Sales and marketing	18,864	986	19,850
General and administrative	5,867	4,081	9,948
	29,079	11,966	41,045
Operating loss	$(6,516)	$(11,966)	$(18,482)

	Commercial Operations Full year	2001 TriPath Oncology July to December	Total
Revenues	$ 27,017	$ –	$ 27,017
Cost of revenues	13,096	–	13,096
Gross profit	13,921	–	13,921
Operating expenses:			
Research and development	6,210	1,079	7,289
Regulatory	1,970	–	1,970
Sales and marketing	18,464	221	18,685
General and administrative	8,661	–	8,661
	35,305	1,300	36,605
Operating loss	$(21,384)	$(1,300)	$(22,684)

All revenues were from external customers. There were no inter-segment revenues. Sales to external customers of the Commercial Operations segment includes the following for the years ended December 31, 2002 and 2001:

	2002	2001
Instruments	$ 6,495	$10,236
Reagents	24,730	10,914
Fee-per-use and other	6,260	5,867
Total revenues	$37,485	$27,017

At December 31, 2002, we had accounts and notes receivable of $2,036 from a company which disclosed to us its intention to exit the cervical cytology business. The contract we have with this customer was a multi-

year agreement that included commitments for reagents and disposables. As we were unable to reach a mutually acceptable settlement under our agreement through negotiations with that company, we filed suit against that company in February 2003 in state court in North Carolina to enforce our rights under the agreement. We believe that company to be credit-worthy and able to satisfy any judgment we may obtain against it. We expect no material adverse financial impact on our results of operations or financial position, although this litigation will result in additional costs to us that we may be unable to recover.

The Commercial Operations segment had depreciation and amortization expense of $3,735 and $3,888 for the 2002 and 2001 financial years, respectively. The TriPath Oncology segment only had depreciation expense of $126 in 2002. The TriPath Oncology segment also received $6,198 in deferred R&D funding from BD, which is being amortized against such expenses over thirty months on a straight-line basis. In 2002 and 2001, respectively, $2,479 and $1,033 of amortization was recorded against R&D expense. Purchases of property and equipment by the Commercial Operations segment for 2002 and 2001 were $1,430 and $775, respectively. For TriPath Oncology, purchases of property and equipment for 2002 and 2001 were $821 and 161, respectively. The TriPath Oncology segment had total assets of $1,912 as of December 31, 2002 and the Commercial Operations segment total assets of $72,039.

Geographic Area Data

Through September 30, 2000, Commercial Operation's domestic revenues were generated primarily by direct sales activities. In October 2000, the segment began a planned expansion of its field sales forces, which included the building of a physician directed sales force. International revenues continue to be derived primarily through distributors. International revenues accounted for 32%, 23% and 32% of total revenues during 2002, 2001 and 2000, respectively. Our largest customer accounted for 8% of total revenue in 2002. In 2001 and 2000, the respective largest customers accounted for 11% and 20% of total revenue.

9. Related Party Transactions

We have a temporary arrangement with BD, a shareholder, for leasing a portion of BD's facility in Research Triangle Park, North Carolina ("RTP"). Total rent paid to BD amounted to $130 during 2002 and $5 during 2001. This arrangement continued, primarily for use of BD's animal laboratory facilities, though on a much-reduced scale after TriPath Oncology occupied its new space in the RTP area of North Carolina in July of 2002.

Included in Notes Receivable is a loan of $27 made to an Officer of the Company.

10. Employee Benefits

We maintain qualified 401(k) Retirement Plans covering substantially all employees that provide for voluntary salary deferral contributions. Total expense for the plans, including employer contributions, amounted to $336, $263 and $249 during 2002, 2001 and 2000, respectively.

Since January 1, 2002, we began offering to employees a qualified Employee Stock Purchase Plan covering substantially all employees that provide for voluntary salary deferral contributions for the purchase of our stock subject to the provisions of the Plan. There was no expense associated with this plan recorded in 2002.

11. Contingencies

In the ordinary course of business, we are the subject of, or party to, various pending or threatened claims and litigation. In the opinion of management, settlement of such claims and litigation will not have a material effect on our operations or financial position.

(In thousands, except share and per share amounts)

12. Quarterly Results of Operations (Unaudited)

2002	March 31	June 30	September 30	December 31
Revenues	$ 7,563	$ 9,132	$ 9,826	$10,964
Gross profit	4,316	5,340	5,940	6,967
Net loss	(5,301)	(5,418)	(4,280)	(3,065)
Net loss per common share (basic & diluted) (1)	$ (0.14)	$ (0.14)	$ (0.11)	$ (0.08)

2001	March 31	June 30	September 30	December 31
Revenues	$ 9,287	$ 6,153	$ 5,250	$ 6,327
Gross profit	4,700	2988	3,002	3,231
Net loss	(3,203)	(4,160)	(7,494)	(6,823)
Net loss per common share (basic & diluted) (1)	$ (0.09)	$ (0.12)	$ (0.21)	$ (0.18)

(1) The sum of per share earnings by quarter may not equal earnings per share for the year due to changes in average share calculations. This is in accordance with prescribed reporting requirements.

EXHIBIT 99.1

TRIPATH IMAGING, INC.

FACTORS AFFECTING FUTURE OPERATING RESULTS

March 2003

From time to time, TriPath Imaging, through its management, may make forward-looking public statements, such as statements concerning then expected future revenues or earnings or concerning projected plans, performance, product development and commercialization as well as other estimates relating to future operations. Forward-looking statements may be in reports filed under the Securities Exchange Act of 1934, as amended, in press releases or in oral statements made with the approval of an authorized executive officer. The words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project" or similar expressions are intended to identify "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933, as enacted by the Private Securities Litigation Reform Act of 1995.

We caution you not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. In addition, we advise you that the factors listed below, as well as other factors we have not currently identified, could affect our financial or other performance and could cause our actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods or events in any forward-looking statement.

We will not undertake and specifically decline any obligation to publicly release revisions to these forward-looking statements to reflect either circumstances after the date of the statements or the occurrence of events which may cause us to re-evaluate our forward-looking statements, except as required by law.

In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, we are hereby filing cautionary statements identifying important factors that could cause our actual results to differ materially from those projected in forward-looking statements made by us or on our behalf.

RISKS RELATED TO OUR BUSINESS

Our oncology products are at an early stage of development and we cannot assure the commercial success of these products.

Our oncology products are in the early stages of development and significant additional research, and development, financial resources and personnel will be required to develop them into commercially viable products and obtain regulatory approvals. We are developing and commercializing molecular diagnostic and pharmacogenomic tests for a variety of cancers through our collaboration with Becton, Dickinson and Company, or BD, as part of the ongoing strategic alliance between BD and Millennium Pharmaceuticals, Inc., or Millennium. Our collaboration with BD has not yet produced a viable product. We may fail to successfully develop and commercialize our oncology products if:

- pre-clinical research shows our products to be ineffective;
- they do not receive necessary regulatory approvals or otherwise meet regulatory requirements; or
- are less effective than current or alternative oncology diagnostic methods.

If we fail to develop and commercialize our oncology products, our revenues could be adversely affected.

Our oncology products business will be negatively affected if BD or Millennium fails to deliver required certain test markers under our collaborative arrangement, or if BD fails to support, or terminates its collaboration with us.

We conduct all of our oncology-related discovery and development activities through our collaboration with BD. TriPath Oncology is developing and commercializing molecular diagnostics and pharmacogenomic

tests for cancer as part of the ongoing strategic alliance of BD and Millennium. The success of our oncology products business depends, in large part, on the fulfillment of the contractual obligations by BD and Millennium, including the delivery of validated genomic and proteomic markers discovered by Millennium under its arrangement with BD. Both BD and Millennium have significant discretion in determining the efforts and resources that they will apply to the collaboration. Our collaboration with BD may not be scientifically or commercially successful. The risks that we face in connection with this collaboration include:

- Millennium may fail to deliver validated markers under its strategic partnership with BD, which TriPath Oncology needs to develop diagnostic oncology products;
- if the collaboration between BD or Millennium is terminated, we may lose rights to certain intellectual property necessary to develop our oncology products; and
- BD or Millennium may choose to develop and commercialize, either alone or with others, products and services that are similar to or competitive with the non-exclusive or co-exclusive products and services that are the subject of the collaboration with us.

If BD or Millennium fail to fulfill their obligations under our collaborative arrangement or if BD terminates the collaboration with us, the future of our oncology products business would be adversely affected.

Our products are subject to regulatory review, approval and regulation and we may be unable to commercialize any of our products currently in development.

The FDA and foreign regulatory agencies extensively regulate the manufacture and sale of medical diagnostic devices for commercial use. We must comply with applicable FDA regulations, including obtaining FDA approval of products before we can market and sell them for their principal intended uses in the United States.

To obtain FDA approval for our products, we must submit a pre-market approval application to the FDA. This process can be expensive and time-consuming and can take several years. Several factors may affect our ability to successfully obtain FDA approval for the commercialization of our products, including the following:

- failure of the product in pre-clinical studies;
- insufficient clinical trial data to support the safety or effectiveness of the product; or
- unanticipated delays or significant unanticipated costs in our efforts to secure FDA approval.

If we fail to obtain and maintain FDA approval for any of our future products, if FDA approval is delayed, or if we receive FDA approval for our products but labeling restrictions make the use of the products uneconomical to our customers, our future product sales will be far less than we anticipate and may be insufficient to sustain our operations. We have no assurance that the FDA will ever approve our future products for their principal intended use. In addition to the pre-market approval application process, we may face further difficulties in connection with FDA approval of our products for the following reasons:

- FDA regulations require submission and approval of a pre-market approval application supplement for certain changes to a product if the changes affect the safety and effectiveness of the product;
- even if we obtain FDA approval of our pre-market approval applications, that approval may still not allow us to make some of the specific claims for which we sought FDA approval; and
- any FDA approval may include significant limitations on the indicated uses for which we may market our products, such as warnings, precautions or contraindications, requests for post-market studies, or additional regulatory requirements.

The FDA may not approve our future products or commercial enhancements to our existing products on a timely basis, if at all. Our regulatory applications also may be delayed or rejected based on changes in regulatory policies or regulations.

Government regulation imposes significant restrictions and costs on the development and commercialization of our products.

Any products approved by the FDA are still subject to continual government review and regulation, so long as the product is being marketed. Of our principal products, PrepStain, FocalPoint and the use of PrepStain with FocalPoint, have received FDA approval. Although we have received FDA approvals, we are still subject to continual FDA review and regulation regarding the ongoing marketing, sale and use of our cervical screening products. During this continual review process, any subsequent discovery of previously unknown or unrecognized problems with the product or a failure of the Company or the product to comply with any applicable regulatory requirements can result in, among other things:

- fines or other civil penalties;
- the refusal of the FDA to approve further pre-market approval applications;
- suspension or withdrawal of our FDA approvals;
- product recalls;
- operating restrictions, including total or partial suspension of production, distribution, sales and marketing of our products;
- injunctions; or
- product seizures and criminal prosecution of us, our officers or our employees.

We depend on a limited number of products and these products may never gain market acceptance.

Sales and rentals of PrepStain and FocalPoint for cervical cancer screening currently account for the substantial majority of our revenues. Market acceptance of PrepStain and FocalPoint, as well as their combined use, will depend on our ability to convince clinical laboratories, physicians, third party payors and other health care providers and consumers that our products can address the limitations of the conventional Pap smear process. We may not be able to successfully establish that our products are better and more cost competitive compared to the conventional Pap smear process. In addition, the market may not accept our cervical cancer products as a replacement to the conventional Pap smear collection process. Even if PrepStain, FocalPoint, and the utilization of PrepStain with FocalPoint and other products do gain market acceptance, their level of sales will still largely depend on the availability and level of reimbursement from third-party payors, such as private insurance plans, managed care organizations and Medicare and Medicaid. There can be no assurance that we will achieve market acceptance for PrepStain, FocalPoint, or their combined use, and the failure to do so would have a material adverse effect on our business, financial condition and results of operations.

In addition, the market may not accept any of the oncology products that we develop. While various diagnostic and pharmacological oncology tests are currently available, few tests offer an integrated solution for diagnosing cancer at the earliest possible stage, providing individualized predictive and prognostic information, guiding treatment selection for patients with cancer, and predicting disease recurrence. Market demand for our oncology products will depend primarily on acceptance by clinical laboratories, physicians and third party payers. Commercial acceptance of our oncology tests will depend upon several factors, including:

- their potential advantage, including their cost-effectiveness over alternative diagnostic methods;
- our ability to compete with similar or superior products developed by our competitors;
- our ability to build and maintain, or access through third parties, a capable sales force; and
- qualification of our products for third party medical insurance coverage and reimbursement.

If our oncology products do not achieve significant market acceptance, our revenues could be adversely affected.

We have a history of operating losses and an accumulated deficit and we may never become profitable.

We have a history of operating losses and we expect losses to continue for the next several years as we continue to market our products, develop new products and perform additional clinical studies. As of December 31, 2002, we had cumulative net losses of approximately $224.5 million. While our products have grown in acceptance as measured by our revenues, we still operate in a very competitive environment. These losses resulted principally from the costs of our research and development activities and expenses in excess of revenues. Our operating expenses have been concentrated in the following areas:

- research and development activities;
- sales and marketing activities, including the cost and effect of promotional discounts, sales, and marketing programs and strategies; and
- regulatory issues, including activities in connection with pre-market approval applications to the FDA.

We expect marketing and sales expenses associated with our products to either continue at their current rate or increase in the future, which could contribute to financial losses for us. These expenses are a result of our expanded marketing and sales efforts to continue the commercial rollout of our products. Our profitability is subject to uncertainty and will depend on a number of factors including:

- receipt of regulatory approvals for future products in a timely manner;
- successful marketing of our products in the United States;
- the extent to which our products gain market acceptance;
- ability to manufacture our products at an acceptable cost and with acceptable quality;
- introduction of alternative technologies by our competitors;
- the timing and volume of system placements;
- availability of reimbursement from third-party payors, and the extent of coverage; and
- ability to establish internal financial controls and other infrastructure necessary to support large-scale commercial operations.

We expect to continue incurring overall net operating losses until product sales and service revenues sufficiently fund our operations and while our oncology business is developing products that can be commercially introduced into the market. We cannot be certain that we will ever become profitable.

We cannot be certain of our future capital needs and additional financing may not be available when we need it.

Since beginning operations, we have financed our operations through the private placement and public sales of equity securities, debt facilities and limited product sales. We have had negative cash flow from operations since inception, and we expect negative cash flow from operations to continue at least through the next 12 to 24 months. At December 31, 2002, we had approximately $32.6 million in cash and cash equivalents. We believe that our existing cash and existing debt and lease financing will be sufficient to enable us to meet our future cash obligations through at least 2004.

We may be unable to obtain adequate funds, either through financial markets or from collaborative or other arrangements with corporate partners or other sources, when we need them, or we may be unable to find adequate funding on favorable terms, if at all. If we are unable to fund our future capital requirements, it would significantly limit our ability to continue our operations.

The extent of our future capital requirements depends on several factors, including:

- the timing of achieving profitability;
- the timing and costs of product introductions;

- the extent of our ongoing research and development programs, including that at TriPath Oncology;
- the progress and scope of clinical trials;
- the timing and costs required to receive both United States and foreign governmental approvals for new products in development;
- the extent to which our products gain market acceptance;
- demand for and sales of our combined PrepStain and FocalPoint systems for cervical cancer screening and of FocalPoint GS in the United States, if and when it gains FDA approval;
- the resources required to further develop our marketing and sales capabilities domestically and internationally, and the success of those efforts;
- the resources required to expand manufacturing capacity;
- the costs of training laboratory personnel to become proficient with the use of our products; and
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

Many of these factors are out of our control. There is no guarantee that the assumptions underlying our estimates about our needs for future capital will prove to be accurate.

Our future financing arrangements may impact the value of your investment or may impact our rights to our intellectual property.

We may choose to raise additional funding to meet our future capital requirements through a variety of financing methods, including lease arrangements, debt or equity financings, or strategic alliances. If we were to raise additional funding through the sale of equity or securities convertible into equity, your proportionate ownership in TriPath Imaging may be diluted. In addition, if we obtain additional funds through arrangements with collaborative partners, we may have to relinquish rights to certain of our technologies or potential products that we would otherwise seek to develop or commercialize ourselves.

If our strategic partnerships are unsuccessful, our earnings growth will be limited.

An important element of our strategy is to enter into strategic partnerships for the research and development of alternative applications for our extensive body of intellectual property. We currently have a strategic arrangement with BD for the development of diagnostic and pharmacogenomic oncology tests and we may enter into additional partnerships in the future. We believe that recent advances in genomics, biology, and informatics are providing new opportunities to leverage our proprietary technology. The success of these arrangements is largely dependent on technology and other intellectual property contributed by our partners, as well as their efforts, resources and skills. Our existing and future strategic partnerships are also dependent upon our partners' continued willingness to collaborate with us, as opposed to our competitors. There can be no assurance that we will succeed in implementing and finalizing any new strategic partnerships to facilitate the exploitation of our intellectual property estate. The failure to do so could have a material adverse effect on our future prospects inside and outside of the cervical cytology or diagnostic oncology markets and could impact our financial condition and results of operations.

We have limited manufacturing experience and capacity and we may not be able to establish sufficient manufacturing capability and capacity, either of which could have a material adverse effect on our business.

We manufacture PrepStain and FocalPoint, and related products either at our Burlington, North Carolina, or at our Redmond, Washington facilities. Currently, we have limited manufacturing experience and capabilities for high volume test kit manufacturing. While we believe we have sufficient capacity to meet near term customer demand for our cervical cytology products, and while we have introduced lean manufacturing into our Burlington, North Carolina operations, we may have to substantially increase our manufacturing

capabilities in the future if our products gain wider market acceptance. We may not be able to recruit and retain skilled manufacturing personnel to establish sufficient manufacturing capability and capacity. Even if we are able to establish sufficient manufacturing capability and capacity, we still may be unable to manufacture our products:

- in a timely manner;
- at a cost or in quantities necessary to make them commercially viable;
- in conformance with quality system requirements; or
- in a manner which otherwise ensures our products' quality.

If we cannot successfully increase our manufacturing capability and capacity, or successfully contract with third parties to manufacture our products, our profitability will suffer.

We may not be able to manufacture our products in a timely or cost effective manner because we depend on single and limited source suppliers for our products' components.

We currently obtain certain components for our products on a single source basis from certain suppliers. If any of these sole-source suppliers are unable to provide an adequate and constant supply of components, we will need to modify any components provided by additional or replacement suppliers. If we are unable to establish additional or replacement sources of supply on a cost-competitive and timely basis from these suppliers, we may need to delay or halt our manufacturing process. If any of the components of our products were no longer available in the marketplace, we could be forced to further develop our technology to incorporate alternate components. We also may try to establish relationships with additional suppliers or vendors for components for our products, so long as we are not prohibited from doing so by any existing contractual obligations. We may not be able to further develop our technology to incorporate new components or establish relationships with additional suppliers or vendors for the necessary components of our products.

In addition, use of any new components or replacement components from alternative suppliers into our products may require us to submit PMA supplements to the FDA. We would then need FDA approval on any PMA supplements we have filed before we could market our products with new or replacement components. Ultimately, we may not be able to successfully develop, obtain, or incorporate replacement components into our products. Even if we were able to successfully incorporate new components into our products, the FDA may not approve these new components quickly, if at all.

We have limited marketing and sales resources which could hurt our ability to become profitable.

During the last quarter of 2000 and throughout 2001, we added to our marketing and sales forces to more effectively market our products. Even with the increased size of our sales force, we may not be able to successfully promote our products to clinical laboratories, health care providers, including physicians, and third-party payors. In addition, we must educate health care providers and third-party payors regarding the clinical benefits and cost-effectiveness of our products because of the market's limited awareness. We may not be able to recruit and retain additional skilled marketing, sales, service or support personnel to help in our achievement these goals when needed.

Our marketing success in the United States and abroad will depend on whether we can:

- obtain required regulatory approvals;
- successfully demonstrate the cost-effectiveness and clinical-effectiveness of our products;
- further develop our direct sales capabilities; and
- establish arrangements with contract sales organizations, distributors and marketing partners.

If we cannot successfully expand our marketing and sales capabilities in the United States and in international markets, we may never become profitable.

We may have difficulty managing the expansion of our operations, and failure to do so will harm our business.

We are experiencing growth in our employee base and in the scope of our operations, and we anticipate that further expansion will be required to achieve growth in our customer base and to develop and seize market opportunities. This expansion could place a significant strain on our senior management team and on our operational and financial resources.

To manage the expected growth of our operations and personnel, we will need to improve existing, and implement new operational and financial systems, procedures, and controls. We also will need to expand, train, and manage our growing employee base as well as expand and maintain close coordination among our sales and marketing, finance, administrative, and operations staff. Further, we may be required to enter into additional relationships with various suppliers and other third parties necessary to our business. A successful continued expansion may also require us to further develop expertise in complex joint venture negotiations. We cannot guarantee that our current and planned systems, procedures, and controls will be adequate to support our future operations, that we will be able to hire, train, retain, motivate, and manage the required personnel or that we will be able to identify, manage, and benefit from existing and potential strategic relationships and market opportunities. If we do not effectively manage the budgeting, forecasting, and other process-control issues presented by such expansion, our business will suffer. If we are unable to undertake new business due to a shortage of staff or resources, our growth will be impeded. Therefore, there may be times when our opportunities for revenue growth may be limited by the capacity of our internal and external resources rather than by the absence of market demand.

In 2001 and 2002, we made some significant changes to our management team and to our Board of Directors. Although we believe that the new members of our management team are currently integrated with the other members of our management team, we cannot assure you that our management team will be able to continue to work together effectively or manage our growth successfully. We believe that the successful integration of our management team is critical to our ability to manage our operations effectively and support our anticipated future growth.

We depend on patents, copyrights, licenses and other proprietary rights to grow our business and we may not be able to adequately protect all of our proprietary rights.

Our long-term success largely depends on our ability to market products that are technologically competitive. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. To protect our proprietary technology, rights and know-how, we rely on a combination of patents, trade secrets, copyrights, and confidentiality agreements.

We currently hold over 100 foreign patents, over 110 U.S. patents and have six additional U.S. patents pending. These patents will expire from 2003 through 2019. Our reliance on patents poses the following risks:

- our pending patent applications may not ultimately issue as patents;
- patents we obtain may not be broad enough to protect our proprietary rights;
- the claims allowed in any of our existing or future patents may not provide competitive advantages for our products;
- competitors may challenge or circumvent our patents or pending applications; and
- in certain foreign countries, protection of our patent and other intellectual property may be unavailable or very limited.

This may make the possibility of piracy of our technology and products more likely. We cannot guarantee that the steps we have taken to protect our intellectual property will be adequate to prevent infringement or misappropriation of our technology. In addition, detection of infringement or misappropriation is difficult.

Even if we do detect infringement or misappropriation of our technology, we may be unable to enforce our proprietary rights, which could result in harm to our business. We may engage in litigation to attempt to:

- enforce our patents;
- protect our trade secrets or know-how;
- defend ourselves against claims that we infringe the rights of others; or
- determine the scope and validity of the patents or intellectual property rights of others.

Any litigation could be unsuccessful, result in substantial cost to us, and divert our management's attention, which could harm our business.

The risk of third-party claims of infringement against us is high because our industry depends on patents and other proprietary rights.

The large role that patents play in our industry in general may pose the following risks for us:

- we cannot be sure that our products or technologies do not infringe patents of competitors that may be granted in the future pursuant to pending patent applications;
- we cannot be sure that our products do not infringe any existing patents or proprietary rights of third parties; and
- we cannot be sure that a court would rule that our products do not infringe any existing third-party patents or that a court would not invalidate any existing patents in our favor.

If a court were to uphold any claims of infringement made by existing patent holders against us, we could then be:

- prevented from selling our products;
- required to pay damages;
- required to obtain licenses from the owners of the patents; or
- required to redesign our products.

In the event that a court was to uphold a claim of patent infringement against us, we may not be able to obtain licenses from the owners of the patents or be able to successfully redesign our products to avoid patent infringement. If we were unable to obtain the necessary licenses or successfully redesign our products, it could seriously harm our ability to become a profitable company.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Such litigation may also cause a diversion of our management's time and attention from our business. Some of our competitors may be able to sustain the financial and other costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

We face special risks related to international sales and operations because we have limited experience in conducting our business in other countries.

We are currently selling our products to customers in Australia, Asia, Canada, Europe, and South America. While we are evaluating marketing and sales channels abroad, including contract sales organizations, distributors and marketing partners, we have very limited foreign sales channels in place. There can be no assurance that we will successfully develop significant international sales capabilities or that, if we establish such capabilities, we will be successful in obtaining reimbursement or any regulatory approvals required in foreign countries. Our international sales and operations may be limited or disrupted by the imposition of government controls, export license requirements, political instability, trade restrictions, changes in tariffs, difficulties in staffing and managing international operations, changes in applicable laws, less favorable

intellectual property laws, longer payment cycles, difficulties in collecting accounts receivable, fluctuations in currency exchange rates and potential adverse tax consequences. Foreign regulatory agencies often establish product standards different from those in the United States and any inability to obtain foreign regulatory approvals on a timely basis, if at all, could have a material adverse effect on our international business operations. Additionally, if significant international sales occur, our business, financial condition and results of operations could be adversely affected by fluctuations in currency exchange rates as well as increases in duty rates. There can be no assurance that we will be able to successfully commercialize our products or any future products in any foreign market.

Our stock price is highly volatile and the value of your investment will likely fluctuate.

Our stock price has, from time to time, experienced extreme price and volume fluctuations. Often these fluctuations are unrelated or disproportionate to our actual operating performance. Many factors could cause the market price of our stock to decline, including:

- failure to successfully implement aspects of our growth strategy;
- failure to achieve revenue and profitability results expected among those in the investment community;
- failure to meet research and development goals related to our products and services;
- technological innovations by our competitors or introductions of competing technologies;
- investor perception of the biotechnology and medical device industry; and
- general technology or biotechnology trends.

Occasionally, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought such a lawsuit against us, even if the lawsuit was without merit, we could incur substantial costs defending the lawsuit. The lawsuit would also divert the time and attention of our management from our business.

Sales of a substantial number of shares of our common stock could cause the market price of our common stock to decline.

Future sales of common stock by us or any significant shareholder could adversely affect the market price of our common stock. For example, the lock-up provision contained in our Securities Purchase Agreement with Roche, our largest shareholder, expired in February 2003. As a result, in addition to 2,950,680 shares owned by Roche and its affiliates that have no lock-up restrictions, and subject to applicable securities laws, Roche may sell up to 2,500,000 shares, the sale of which was previously restricted, during the 12 months following February 2003, and may sell up to an additional 2,500,000 shares, the sale of which was also previously restricted, during the 12 months following February 2004. If Roche sells all or a significant portion of these shares, our stock price may decline. There can be no assurance that Roche will not attempt to sell all or most of its shares and the value of your investment may fluctuate as a result of such sales.

In addition, if we sell any equity securities, the market price of our common stock could be adversely affected.

Our significant stockholders have the ability to influence significant decisions regarding our future.

Roche is our single largest stockholder. As of March 5, 2003, Roche beneficially owned approximately 21% of our outstanding common stock. Roche also has the right to purchase 5,000,000 additional shares of our common stock through the exercise of warrants and has certain anti-dilution rights with respect to these warrants in order maintain its existing level of ownership. Roche also has the right to designate one member of our Board of Directors. In addition, as of March 5, 2003, BD beneficially owned approximately 7% of our outstanding common stock. As a result, those significant stockholders are able to significantly influence all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership could also delay or prevent a change in control of us that may be favored by other stockholders.

RISKS RELATED TO OUR INDUSTRY

We may be unable to attain or maintain the required compliance with regulations governing manufacturing of medical diagnostic devices.

Manufacturers of medical diagnostic devices face strict federal regulations regarding the quality of manufacturing. For example, the FDA periodically inspects the manufacturing facilities of diagnostic device manufacturers to determine compliance with regulations. Our current and future manufacturing and design operations must comply with these and all other applicable regulations, including regulations imposed by other governments. If we fail to comply with quality systems regulations we could face civil or criminal penalties or enforcement proceedings. These proceedings may require us to recall a product, to stop placing our products in service or to stop selling our products. Similar results could occur if we violate equivalent foreign regulations. We may not be able to attain or maintain compliance with quality systems requirements. Any failure to comply with the applicable manufacturing regulations would have a material adverse effect on our business.

If we are unable to keep up with technological change, our products or services may become obsolete.

Competition in the medical device industry is intense. The diagnostic market for cervical cancer currently consists of both the conventional Pap smear procedure and new and developing technologies. Some of these newly-developed technologies have already received FDA approval with product labeling that has been marketed as more effective than the conventional Pap smear for the detection of disease in certain patient populations. Within the diagnostic market for cervical cancer, we face direct competition from companies that manufacture thin-layer slide preparation or automated screening systems. Our products could be rendered obsolete or uneconomical because of:

- technological advances by current or future competitors;
- the introduction and market acceptance of competitors' products; or
- the introduction and market acceptance of new cervical cancer detection methods.

We may not be able to successfully compete against companies marketing products based on competing technologies. Certain of our existing and potential competitors may have several competitive advantages over us because they:

- possess greater financial, marketing, sales, distribution and technological resources;
- have more experience in research and development, clinical trials, regulatory matters, customer support, manufacturing and marketing;
- have received third-party payor reimbursement for their products; or
- they may collaborate or merge with other competitors in our industry and leverage their combined intellectual property and resources against us.

These competitors may manufacture, market and sell their products or services more successfully than us, which could adversely affect our product sales.

Our products must remain competitive in accuracy and effectiveness, cost, including both charges by us to the laboratory and the laboratory's labor and overhead costs, convenience, perception among influential opinion leaders, including cytopathologists, other physician groups, and laboratories, and processing speed and reliability. To effectively compete, we must keep pace with the product development and technological change in our industry. Our products must demonstrate accuracy and cost effectiveness that equals or exceeds conventional preparation and review of Pap smears and the technology that may be offered by our competitors. We cannot guarantee that our products will be competitive in any of these areas.

If we fail to obtain adequate levels of third-party reimbursement for our products, the commercial success of our products will be significantly limited.

Our ability to successfully sell our products for cervical cancer screening in the United States and other countries depends on the availability of adequate reimbursement from third-party payors such as private

insurance plans, managed care organizations and Medicare and Medicaid. Virtually all of our revenues will be dependent on customers who rely on third party reimbursement. Third-party healthcare payors in the United States are increasingly sensitive to containing healthcare costs and heavily scrutinize new technology as a primary factor in increased healthcare costs. Third-party payors may influence the pricing or perceived attractiveness of our products and services by regulating the maximum amount of reimbursement they provide or by not providing any reimbursement. Medical community or third-party healthcare payors may deny or delay acceptance of our products or may provide reimbursement at levels that are inadequate to support adoption of our technologies.

If these third-party payors do not reimburse for our preparation and screening products, or only provide reimbursement significantly below the amount laboratories charge patients to perform screening with our products, our potential market and revenues will be significantly limited. Use of our products may never become widely reimbursed, and the level of reimbursement we obtain may never be sufficient to permit us to generate substantial revenue.

A significant part of our strategy is to market PrepStain and FocalPoint together. To successfully market FocalPoint and PrepStain together, two Common Procedural Terminology Codes, or CPT codes, were established covering the combined use of these products by the Center for Medicare and Medicaid Services ("CMS"). These CPT codes are applicable to the combined use of our SurePath slides screened using our FocalPoint slide profiler. Also included in the CMS announcement were tentative payment determinations which were finalized on November 8, 2002. The payment determination for the cytopathology tests provides for an appropriate reimbursement amount by combining current payment amounts for the liquid based slide preparations and a portion of either of the two codes that represent the automated screening system. CMS issued a Program Memorandum with instructions on the 2003 Clinical Laboratory Fee Schedule to its carriers and intermediaries on November 8, 2002. There can be no assurance, however, that the laboratories claiming reimbursement under these CPT codes will be successful in obtaining favorable reimbursement.

Convincing third-party payors to provide reimbursement is a costly and time consuming process because reimbursement approval is required from each payor individually; and obtaining this approval from the third-party payor typically requires the presentation of scientific and clinical data to support the use of the products. Whether a third-party payor is willing to provide reimbursement for the use of our products at a level that can allow our company to succeed depends on several unpredictable factors, including:

- the level of demand for our products by physicians;
- the payor's determination that our products are an improvement over the conventional Pap smear process; and
- the payor's determination that our products are safe and effective, medically necessary, appropriate for specific patient populations, and cost effective.

We may face particular difficulties convincing third-party payors that our products are cost effective because the up-front, direct costs of using the products will initially be greater than the cost of the conventional Pap smear. As a result, we will need to convince third-party payors that the use of our products will result in a net overall cost savings to the health care system.

We can only sell our products to a limited number of customers.

A significant portion of our product sales will be concentrated among a relatively small number of large, and medium-sized, clinical laboratories. Moreover, due to consolidation in the clinical laboratory industry, we expect that the number of potential domestic customers for our products may decrease. These factors increase our dependence on sales to the largest clinical laboratories and the bargaining power of those potential customers. Our market research indicates that nearly 40% of all U.S. Pap smears are processed by the two largest laboratories. Each of these companies operates multiple laboratory facilities nationwide.

We will have to make this number of potential customers aware of our products and then convince them to accept and use our products. To gain acceptance of our products within this small customer base, we will have to successfully demonstrate the benefits of our products over the conventional Pap smear process and

other alternative methods of sample collection, slide preparation and cervical cancer screening. In addition, to generate demand for our products among these clinical laboratories, we believe that we must:

- educate doctors and health care providers on, and convince them of, the clinical benefits and cost-effectiveness of our products; and
- demonstrate to doctors and health care providers that adequate levels of third-party payor reimbursement will be available for our products.

Ultimately, we may not be able to successfully sell our products to large clinical laboratories. Even if we do successfully sell our products to large clinical laboratories, those sales may not generate enough revenue to make us a profitable company.

We are at risk of product liability claims and may be unable to maintain adequate insurance against such liabilities.

The commercial screening of Pap smears has historically generated significant malpractice litigation. As a result, we face product liability, errors and omissions or other claims if our products are alleged to have caused a false- negative diagnosis. Although we have product liability insurance, it could become increasingly difficult for us to obtain and maintain product liability coverage at a reasonable cost or in amounts sufficient to protect us against potential losses. If we are unable to obtain adequate product liability insurance at a reasonable cost a successful product liability claim or a series of claims brought against us could require us to pay substantial amounts that would decrease our profitability, if any.

Our success depends on our ability to retain our key personnel.

We will depend heavily on the principal members of our management and scientific staff. The loss of their services might impede achievement of our strategic objectives or research and development. Our success depends on our ability to retain key employees and to attract additional qualified employees, which may be particularly difficult to do in the future. Competition for highly skilled scientific and management personnel is intense, particularly in the geographic areas in which we currently are located, and these resources are scarce relative to the needs of a growing high technology business sector. The failure to recruit such personnel or the loss of existing personnel could adversely affect our business.

CORPORATE INFORMATION

CORPORATE OFFICERS

Paul R. Sohmer, M.D.
President, Chief Executive Officer and Chairman of the Board

Stephen P. Hall
Senior Vice-President and Chief Financial Officer

Johnny D. Powers, Ph.D.
Vice-President and General Manager, TriPath Oncology

Ray W. Swanson
Senior Vice-President, Commercial Operations

BOARD OF DIRECTORS

Paul R. Sohmer, M.D.
Chairman of the Board

Thomas A. Bonfiglio
Senior Attending Pathologist and Head, Division of Pathology at The Rochester General Hospital

Haywood D. Cochrane, Jr.
President and Chief Executive Officer, Meridian Corporate Healthcare

Robert E. Curry, Ph.D.
Venture Partner, Alliance Technology Ventures

Robert L. Sullivan
Past Senior Vice-President of Finance, Chiron Diagnostics Corporation

Registrar and Transfer Agent
American Stock Transfer & Trust Company, Inc.
59 Maiden Lane
New York, New York 10038

Our transfer agent is responsible for handling shareholder questions regarding lost stock certificates, address changes, and changes of ownership or name in which shares are held.

Copies of our Form 10-K, Forms 10-Q, our quarterly earnings releases, or other recent news releases may be obtained through our corporate homepage, www.tripathimaging.com, or by writing to:

Investor Relations
TriPath Imaging, Inc.
780 Plantation Drive
Burlington, North Carolina 27215

Independent Auditors
Ernst & Young, LLP
Raleigh, North Carolina

Legal Counsel
Palmer & Dodge, LLP
Boston, Massachusetts

Stock Symbol
TriPath Imaging common stock trades on the Nasdaq National Market under the symbol "TPTH."

Annual Meeting
The annual meeting of shareholders will be held on Thursday, May 22, 2003 at 10:00 A.M. at the Country Suites, 3211 Wilson Drive, Burlington, North Carolina.

Designed by Curran & Connors, Inc. / www.curran-connors.com

TRIPATH IMAGING, INC.

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