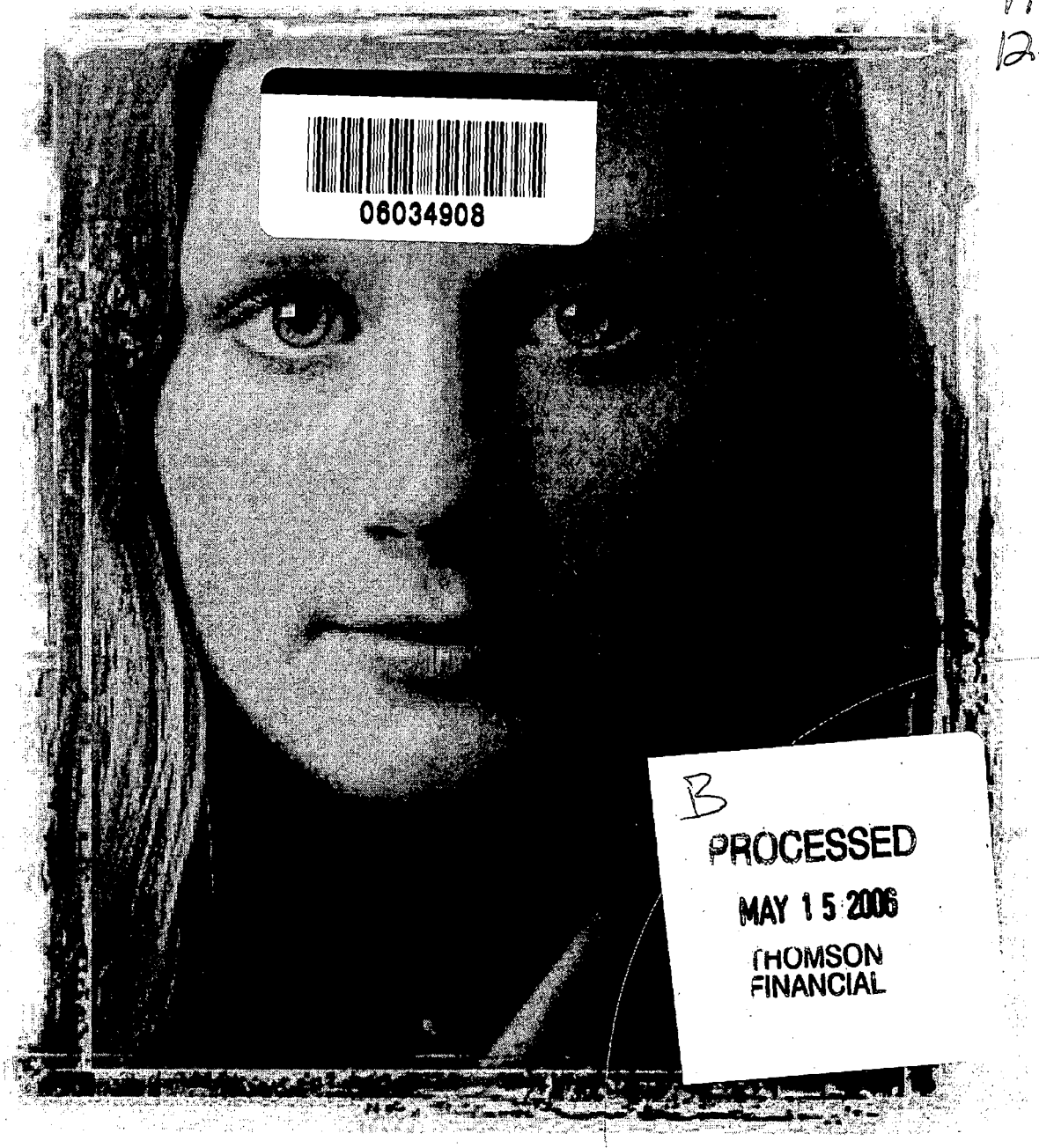
AR/S

Results

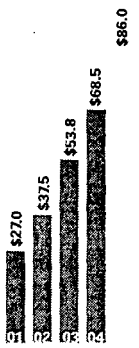
IN THE REAL WORLD

P.E. 12-31-05

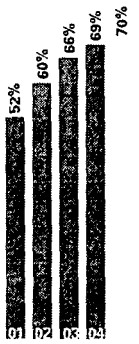


TRIPATH IMAGING, INC. 2005 ANNUAL REPORT

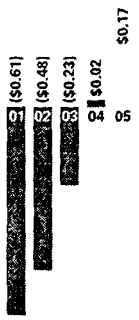
TRIPATH IMAGING



Revenues
in millions



Gross Margin
percent



Earnings/(Loss) Per Share

CORPORATE PROFILE: TriPath Imaging, Inc., headquartered in Burlington, North Carolina, develops, manufactures, markets and sells innovative solutions to improve the clinical management of cancer, including detection, diagnosis, staging and treatment. TriPath Oncology, a wholly owned subsidiary of TriPath Imaging, develops molecular diagnostic products for malignant melanoma and cancers of the cervix, breast, ovary and prostate.

Nasdaq National Market: TPTH

Total Revenues Increased Nearly

26%

We create solutions that redefine the early detection and clinical management of cancer.

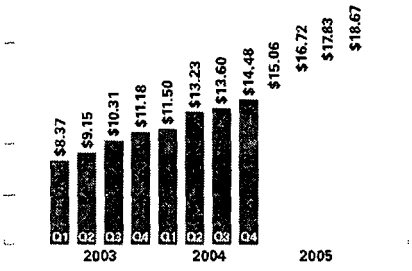
Selected Consolidated Financial Data[1]

Statement of Operating Data Years ended December 31 *(In thousands, except per share data)*	2001	2002	2003	2004	2005
Revenues	$ 27,017	$ 37,485	$53,764	$68,504	$85,961
Gross profit	13,921	22,563	35,387	47,274	59,926
Research and development [2]	7,828	10,259	14,295	15,162	15,755
Selling, general and administrative	28,777	30,786	30,011	31,778	37,992
Operating income/(loss)	(22,684)	(18,482)	(8,919)	334	6,179
Net income/(loss)	$(21,680)	$(18,064)	$ (8,538)	$ 605	$ 6,500
Earnings/(loss) per share (diluted) [3]	$ (0.61)	$ (0.48)	$ (0.23)	$ .02	$ .17
Weighted-average shares outstanding (diluted)	35,467	37,438	37,626	39,151	39,270

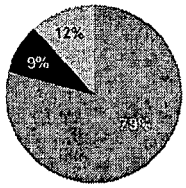
Balance Sheet Data As of December 31 *(In thousands)*	2001	2002	2003	2004	2005
Cash, cash equivalents and short-term investments	$ 55,976	$ 32,571	$20,954	$18,949	$22,457
Working capital	62,898	38,837	33,446	35,909	42,261
Total assets	96,748	73,951	65,928	67,534	76,968
Long-term obligations	5,001	220	8	–	98
Total stockholders' equity	$ 77,291	$ 59,177	$52,371	$58,546	$65,959

(1) The selected consolidated financial data presented above should be read in conjunction with Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto, each of which is included in our Annual Report on Form 10-K for the year ended December 31, 2005.
(2) Includes regulatory expenses.
(3) See Note 2 of Notes to our consolidated financial statements for information concerning the computation of earnings/(loss) per share and shares used in computing earnings/(loss) per share.

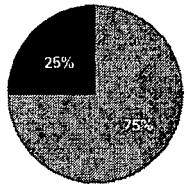
FINANCIAL Results



Steady Growth in Reagent Revenues
in millions



2005 Revenue Mix
- Reagents
- Instruments
- Other

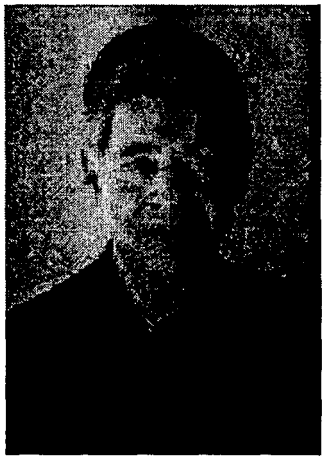


2005 Geographic Revenue Breakdown
- United States
- International

Results IN THE REAL WORLD

WE GENERATED NET INCOME OF $6.5 MILLION

TO OUR SHAREHOLDERS: Our performance in 2005, once again, clearly demonstrated the fundamental strengths of our business. We grew our revenues by nearly 26%; we generated net income of $6.5 million, a $5.9 million improvement from the prior year; we grew operating income from our cytology business by 50%, and; we moved new molecular oncology products through internal and external research studies, into clinical trials, and into the marketplace while generating significant revenues from the sale of some of these molecular products for the first time in our history.



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

We continued to leverage our cytology business. We drove nearly $22.1 million in operating income from our commercial operations segment, a $7.3 million improvement from the prior year, as revenues generated from the sale of our SurePath™ liquid based Pap test and sales, rental, and usage fees associated with the FocalPoint™ Imaging System grew 24% from 2004.

Tangible evidence of the progress that we made in our molecular oncology business was reflected in the array of products that we introduced; the presentation and publication of data generated from internal and external research studies employing our molecular reagents and imaging systems; the transition of our microscopic slide-based assays into clinical trials; the completion of the development of our ELISA formatted blood-based research use only reagents for ovarian screening, and; revenues generated from the early commercialization of some of our microscopic slide-based reagents, our reagent enabling products, and VIAS, the Ventana Medical Systems' branded version of our interactive histology imaging system.

SUREPATH™ ADOPTION CONTINUES TO GROW

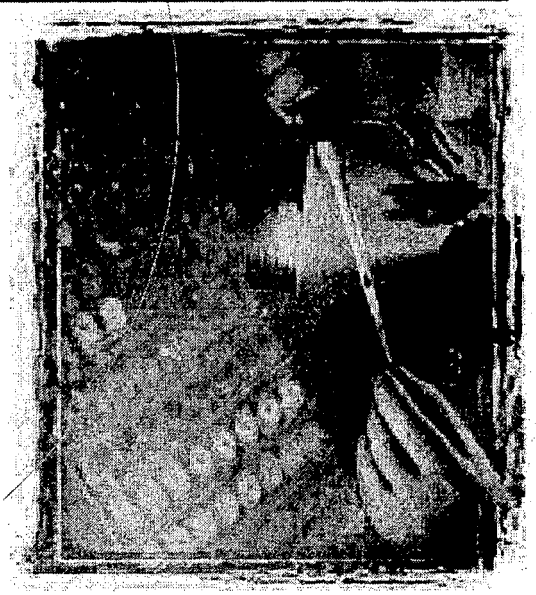
Adoption of the SurePath™ liquid based Pap test continued to grow both in the U.S. and abroad. The number of SurePath™ liquid based Pap tests sold in 2005 grew over 41% in the U.S. and nearly 26% outside the U.S.

We estimate that by year-end, the SurePath™ liquid based Pap test accounted for 21.5% of all Pap tests performed in the U.S. Our growing relationship with the large commercial laboratories in the U.S. was a major driver of our domestic growth as the number of tests sold to this market segment grew 140% from 2004. Our expanded U.S. sales force of more than 100 sales professionals and application specialists has enabled us to leverage the opportunity for growth among the large commercial laboratories as well as from our traditional customer base.

Worldwide Reagent
Sales Increased

30%

Cash Flow Positive In All Quarters Of 2005



The SurePath™ liquid based Pap test continued to gain traction outside the U.S. as well. The number of SurePath™ tests sold increased 45% in Europe, 30% in Asia and 8% in Canada. Particularly noteworthy has been the progress that we have made in the U.K., where by year-end our local distributor had been awarded contracts to supply the SurePath™ liquid based Pap test for cumulative commitments of over 36% of the Pap test market in the U.K., 38% in England and Wales.

THE MOLECULAR PIPELINE BEGINS TO FILL

In 2005, we began to fill our pipeline of molecular products. We initiated early commercialization of an array of these products, including our ProEx C microscopic slide-based analyte-specific reagent for aberrant S phase induction (aberrant S phase induction is associated with cancer of the cervix, esophagus, ovary, lung and prostate), our ProEx Br microscopic slide-based analyte-specific reagents for proteins expressed in breast cancer, our cervical cancer staging assay (outside the U.S.) and our molecular staining system. In addition, Ventana Medical Systems, Inc. initiated the commercial introduction of VIAS, the Ventana branded version of our interactive histology imaging system, that received FDA 510(k) clearance for processing of Ventana estrogen and progesterone receptor and Her-2/neu assays.

Concurrently, we continued to collect data from both in-house and external research studies employing our microscopic slide-based research use only reagents for breast and cervical cancer staging. On the strength of these data we initiated clinical trials designed to support FDA submissions in late 2006 and 2007. As 2005 came to a close, we completed the development of our first blood-based reagents, our ELISA formatted blood-based research use only reagents for ovarian screening.

SUREPATH™ SALES IN EUROPE INCREASED 45%

Results

FOR LABORATORIES

WE'LL LEVERAGE OUR CTYOLOGY BUSINESS

Results

FOR CLINICIANS

AN AMBITIOUS AGENDA FOR 2006

Given the fundamental strengths that we again demonstrated in 2005, we have set a very ambitious agenda for 2006:

We expect to continue to leverage our cytology business and to drive increased operating income from our commercial operations segment on growth in sales of both our SurePath™ liquid based Pap test and the FocalPoint™ Imaging System;

We expect that our most significant new investment in 2006 will relate to our clinical trials. Our recently reconstituted regulatory and clinical affairs team will remain very active throughout 2006. We expect to collect data in support of FDA submissions relating to our FocalPoint™ GS Imaging System for cervical cytology screening, our microscopic slide-based assay for breast cancer staging, and the SurePath™ Molecular Pap test;

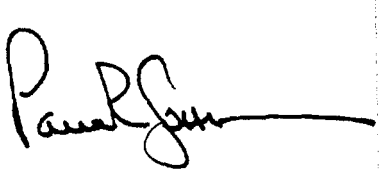
We expect to continue to drive the early commercialization of our molecular products that were released in 2005 by introducing Class I IHC kits that incorporate our ProEx C biomarkers and by expanding the VIAS testing menu;

We expect to receive data from both in-house and external research studies employing our ELISA formatted research use only reagents for ovarian screening; and;

We expect to ready our blood-based ovarian screening assay for pivotal clinical trials in 2007 by adapting this assay to a multiplexing testing platform that will allow for simultaneous detection of multiple markers in a very small volume of blood.

In 2006, we expect to continue to build on the fundamental strengths that we demonstrated in 2005. Our success will be determined by the extent to which we continue to leverage our commercial operations segment and the progress that we make in commercializing our growing pipeline of molecular diagnostic products. We believe that we accomplished a great deal in 2005 and are looking forward to another profitable and productive year in 2006.

As always, we wish to thank our stockholders, our customers and our employees for their ongoing commitment and support.



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

Operating Income From Our Cytology Business Grew

50%

Consolidated Balance Sheets

December 31 *(In thousands, except share and per share amounts)*	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,457	$ 18,949
Accounts and notes receivable, net	15,647	12,976
Net investment in sales-type leases	828	667
Inventory, net	12,564	10,723
Other current assets	1,676	1,582
Total current assets	53,172	44,897
Customer use assets, net	8,044	7,688
Property and equipment, net	4,556	3,290
Other assets	2,362	2,734
Net investment in sales-type leases, net of current portion	1,807	1,043
Patents, less accumulated amortization of $4,433 and $3,752 at December 31, 2005 and 2004, respectively	5,111	5,792
Other intangible assets, less accumulated amortization of $1,427 and $1,229 at December 31, 2005 and 2004, respectively	1,916	2,090
Total assets	$ 76,968	$ 67,534
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,459	$ 3,668
Accrued expenses	5,323	3,750
Deferred revenue and customer deposits	1,106	1,551
Obligations under capital lease	23	—
Current portion of debt	—	19
Total current liabilities	10,911	8,988
Long-term portion of obligations under capital lease	98	—
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; 38,324,632 and 38,127,501 shares issued and outstanding at December 31, 2005 and 2004, respectively	383	381
Additional paid-in capital	291,561	290,114
Deferred compensation	—	(11)
Accumulated deficit	(225,915)	(232,415)
Accumulated other comprehensive income	11	477
Treasury stock, at cost, 10,000 shares and 0 shares at December 31, 2005 and 2004, respectively	(81)	—
Total stockholders' equity	65,959	58,546
Total liabilities and stockholders' equity	$ 76,968	$ 67,534

See Notes to Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2005

Consolidated Statements of Operations

Years Ended December 31 *(In thousands, except per share amounts)*	2005	2004	2003
Revenues	$85,961	$68,504	$53,764
Cost of revenues	26,035	21,230	18,377
Gross profit	59,926	47,274	35,387
Operating expenses:			
Research and development	12,352	11,280	8,861
Regulatory	3,403	3,882	5,434
Sales and marketing	24,440	18,640	18,324
General and administrative	13,552	13,138	11,687
	53,747	46,940	44,306
Operating income/(loss)	6,179	334	(8,919)
Interest income	605	289	413
Interest expense	(9)	(18)	(32)
Income/(loss) before income taxes	6,775	605	(8,538)
Income taxes	275	—	—
Net income/(loss)	$ 6,500	$ 605	$ (8,538)
Earnings/(loss) per common share			
Basic	$ 0.17	$ 0.02	$ (0.23)
Diluted	$ 0.17	$ 0.02	$ (0.23)

See Notes to Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2005

FINANCIAL Results

Consolidated Statements of Cash Flows

Years Ended December 31 *(In thousands)*	2005	2004	2003
OPERATING ACTIVITIES			
Net income/(loss)	$ 6,500	$ 605	$ (8,538)
Adjustments to reconcile net income/(loss) to net cash provided by (used in) operating activities:			
Depreciation	4,394	4,097	3,539
Amortization of intangible assets	879	830	817
Amortization of deferred compensation	11	11	26
Provision for doubtful accounts	50	3	180
Reserve for obsolete and slow-moving inventory	(308)	75	400
Non-cash equity compensation	—	—	49
Amortization of non-cash sales discount	1,278	519	—
Amortization of deferred research and development	—	(207)	(2,479)
Loss on disposal of fixed assets	—	24	13
Provision for income taxes	91	—	—
Changes in operating assets and liabilities:			
Accounts, notes and lease receivables	(2,994)	196	(4,363)
Inventory	(5,941)	(3,588)	(3,522)
Other current assets	(102)	702	(1,011)
Other long-term assets	(1,170)	(692)	443
Accounts payable and accrued expenses	2,309	(4,521)	3,927
Deferred revenue and customer deposits	(444)	46	395
Other current liabilities	—	—	(2,410)
Net cash provided by (used in) operating activities	4,553	(1,900)	(12,534)
INVESTING ACTIVITIES			
Purchases of property and equipment	(1,588)	(1,215)	(146)
Additions to other intangible assets	(24)	(319)	—
Other	—	(7)	196
Net cash (used in) provided by investing activities	(1,612)	(1,541)	50
FINANCING ACTIVITIES			
Issuance of common stock under employee stock purchase plan	235	246	359
Proceeds from exercise of stock options and warrants	715	969	1,235
Purchase of Company stock	(81)	—	—
Proceeds from debt	—	365	633
Payment of capital lease obligations	(14)	—	—
Payments on debt and leases	(19)	(394)	(1,384)
Net cash provided by financing activities	836	1,186	843
Effect of exchange rate changes on cash	(269)	250	24
Net increase (decrease) in cash and cash equivalents	3,508	(2,005)	(11,617)
Cash and cash equivalents at beginning of year	18,949	20,954	32,571
Cash and cash equivalents at end of year	$ 22,457	$ 18,949	$ 20,954
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for interest	$ 9	$ 18	$ 32
Cash paid for income taxes	184	—	—
NONCASH INVESTING AND FINANCING ACTIVITIES			
Issuance of warrants as consideration under incentive sales agreement	$ 499	$ 3,896	$ —
Capital lease obligations incurred	135	—	—

See Notes to Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2005

CORPORATE INFORMATION

Headquarters
TriPath Imaging, Inc.
780 Plantation Drive
Burlington, NC 27215
(866) TRI-PATH
www.tripathimaging.com

CORPORATE OFFICERS

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

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

Johnny D. Powers, Ph.D.
Senior 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

Haywood D. Cochrane, Jr. (1)
Vice Chairman, I-trax, Inc.

Robert E. Curry, Ph.D. (2)
Venture Partner, Alliance Technology Ventures

Richard A. Franco, R. Ph. (2) (3)
President, The Richards Group, Ltd.; Co-founder, LipoScience, Inc.; Former Chairman, President and CEO, LipoScience, Inc.; Former President and CEO, Trimeris, Inc.; Former Vice President and General Manager, Glaxo, Inc.

Arthur T. King, Ph.D. (2) (3)
Retired Dean, School of Business and Economics Winston-Salem State University

Gail Lieberman (1)
Managing Partner Rudder Capital, LLC

Robert L. Sullivan (1) (3)
Retired Senior Vice President of Finance, Chiron Diagnostics Corporation

(1) Audit Committee member
(2) Compensation Committee member
(3) Nominating and Governance Committee member

REGISTRAR AND TRANSFER AGENT

American Stock Transfer & Trust Co.
59 Maiden Lane
New York, New York 10038
(800) 937-5449
www.amstock.com

The Transfer Agent is responsible for handling registered shareholder questions regarding lost stock certificates, address changes, and changes of ownership or name in which shares are held.

INVESTOR INFORMATION

Copies of the Company's Form 10-K, Forms 10-Q, quarterly earnings releases, or other recent news releases may be obtained through the corporate homepage, www.tripathimaging.com, by calling (866) TRI-PATH or by writing to:

Investor Relations
TriPath Imaging, Inc.
780 Plantation Drive
Burlington, North Carolina 27215
investorrelations@tripathimaging.com

INDEPENDENT AUDITORS

Ernst & Young, LLP
Raleigh, North Carolina

LEGAL COUNSEL

Edwards Angell 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 Wednesday, May 31, 2006, at 10:00 A.M. at the Country Suites, 3211 Wilson Drive, Burlington, North Carolina.

ANNUAL REPORT INFORMATION

The 2005 Annual Report is presented using a summary format intended to provide information about TriPath Imaging in a concise manner. The audited financial statements and detailed analytical schedules are contained in TriPath Imaging's Annual Report on Form 10-K for the year ended December 31, 2005.

Copies of the Form 10-K are being distributed to shareholders together with and as part of the 2005 Annual Report. Additional copies of the Form 10-K are available by contacting the Investor Relations Department.

FORWARD-LOOKING STATEMENTS

Investors are cautioned that 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. Such forward-looking statements include, without limitation, those related to the efficacy and market acceptance of TriPath Imaging's products, TriPath Imaging's product development efforts, TriPath Imaging's ability to maintain and grow its business, the anticipated timing of product launches, and expected drivers of growth. Important factors that may affect TriPath Imaging's operating results include, without limitation: TriPath Imaging may not receive revenues when or in the amounts anticipated; TriPath Oncology and its collaborators may not prioritize or launch products as or when expected; TriPath Imaging and TriPath Oncology's products may not receive FDA or other required regulatory approval when expected, if at all; TriPath Imaging may be unable to increase sales and revenues at its historical rates; expenses may exceed expectations and TriPath Imaging may not maintain profitability; changes in general economic conditions or the healthcare industry may occur that adversely affect TriPath Imaging's customers' purchasing plans; TriPath Oncology may be unable to successfully develop and commercialize products when anticipated, if at all; TriPath Imaging's products may not achieve market acceptance to the degree anticipated; competition and competitive pricing pressures may limit TriPath Imaging's flexibility with respect to the pricing of its products; TriPath Imaging may need to obtain additional financing in the future; TriPath Imaging may not be able to develop and to protect adequately its proprietary technology; and other risks detailed in TriPath Imaging's filings with the Securities and Exchange Commission, including those described in TriPath Imaging's Annual Report on Form 10-K for the year ended December 31, 2005.

Results

IN THE REAL WORLD

Results

IN THE REAL WORLD

TRIPATH IMAGING, INC.
780 Plantation Drive
Burlington, NC 27215
(336) 222-9707
www.tripathimaging.com
Nasdaq National Market: TPTH

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2005

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 incorporation or organization)	*(I.R.S. Employer Identification Number)*

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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is required to file reports Section 13 or 15(d) of the Exchange Act. Yes ☑ No ☐

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (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 30, 2005 was: $258,573,675.

There were 38,382,639 shares of the registrant's Common Stock outstanding as of February 27, 2006.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement of the Registrant for the Registrant's 2006 Annual Meeting of Shareholders to be held on May 31, 2006, 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, 2005, are incorporated by reference into Part III of this Form 10-K.

TriPath Imaging, Inc.

Table of Contents

Part I.

Part II.

Part III.

Part IV.

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

We have registered trademarks in the United States for SurePath®, PrepStain®, FocalPoint®, AutoCyte®, AutoCyte Quic®, CytoRich®, ImageTiter®, PrepMate®, SlideWizard®, and TriPath Imaging®. We have pending U.S. trademark applications for ProEx™, SureDetect™, and TriPath Oncology™. Foreign registrations are maintained for several of our trademarks in Argentina, Australia, Brazil, Canada, Chile, China, the European Union, Hong Kong, Indonesia, Israel, Japan, Malaysia, Norway, the Russian Federation, South Africa, Switzerland, Taiwan and the United Kingdom. We have pending foreign trademark applications for ProEx™ and SureDetect™. In addition to trademark activity, we include 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. All other products and company names are trademarks of their respective holders.

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 Estimates and Certain Factors that May Affect Operating Results "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 Annual Report on Form 10-K. As soon as reasonably practical after they are filed or furnished with the SEC, the Company makes available free of charge on its website, or provides a link to, the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed or furnished with the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. To access these filings, go to the Company's website and click on "Investor Resources," then click on "SEC Filings." Alternatively, interested parties may request, in writing, a copy of this Form 10-K, without charge. Such requests should be made to TriPath Imaging, Inc., Attn: Investor Relations, 780 Plantation Drive, Burlington, North Carolina 27215.

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 expertise 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 our efforts to develop new molecular diagnostic products for malignant melanoma and cancers of the cervix, breast, ovary, and prostate.

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 current products; and (2) TriPath Oncology, our wholly-owned subsidiary, through which we manage the development and market introduction of molecular diagnostic products for cancer.

Our Commercial Operations unit is a commercial engine organized to grow sales, drive margin and generate cash. TriPath Oncology is the development engine of a broad based gene discovery program created to develop new molecular products for the early detection and clinical management of cancer. Today, our revenues are primarily generated through our Commercial Operations unit from the sale of our cervical cytology screening products, and in particular, the SurePath liquid-based Pap test. In 2005, for the first time in our history, we generated significant revenues from the sale of some of the molecular products that we are developing in TriPath Oncology. In 2006, we expect to continue to generate revenues from the early commercialization of TriPath Oncology's molecular diagnostic products and molecular imaging systems and we believe that sales related to these developing products will significantly impact our growth in the future.

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

Our Products

Cervical Cytology Product Line

Our cervical cytology product line includes the following products:

The SurePath Test Pack

Our *SurePath Test Pack* is a proprietary, liquid-based cytology sample collection, preservation and transport system that consists of the SurePath liquid-based Pap test, a sample collection vial, preservative solution and sample collection device. SurePath addresses errors in cell sample collection and slide preparation while providing a liquid medium for performing additional laboratory tests. SurePath slides show a statistically significant reduction of unsatisfactory cases compared to conventional slides. During a clinical exam, a physician or nurse will collect a sample of endocervical and ectocervical cells, using a cervical broom or spatula and brush combination 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 all of the cells collected. The lid of the vial is then fastened and the vial is then transported to a clinical laboratory for follow-on processing on the PrepStain system. The SurePath liquid-based Pap test 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 obtained by using the SurePath Test Pack is layered onto the slide and stained by a prep technician. In May 2003, we received FDA approval for expanded labeling claims to include study data showing a 64.4% ($p<0.00001$) increase in detection of High Grade Squamous Intraepithelial and more serious lesions (HSIL+), as compared to the conventional Pap smear. In June 2004, we received FDA approval for expanded labeling claims to include the use of the spatula and brush combination device for collecting cervical cells as an alternative to the previously approved cervical broom collection device. All SurePath devices come with detachable heads to ensure 100% of the collected sample is sent to the laboratory for processing.

PrepStain Slide Processor

Our *PrepStain Slide Processor* is an automated slide preparation system that produces slides with a standardized, thin-layer of stained cervical cells. It 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 homogenized and 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. Excess blood, inflammatory cells and other debris are removed from the cell suspension using density gradient centrifugation. Once centrifugation is completed, the laboratory technician places the centrifuge tubes 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-millimeter diameter circle. The PrepStain Slide Processor, or PrepStain, reduces the complexity of interpretation by providing a homogeneous, more representative and standardized thin layer of stained cells. The FDA approved PrepStain in June 1999. In early 2005, we received FDA approval for expanded claims to include the processing of pre-coated slides, which are branded as SurePath® PreCoat slides. The PreCoat slide is intended to provide our customers with a pre-charged slide that is ready to use, directly from the package. The product is intended to replace TriPath's current uncoated slides and the Slide Coat reagent currently utilized in our GYN and Non-GYN kits.

The *PrepMate* system, an accessory to PrepStain, is designed to automate pre-processing steps in the preparation of SurePath thin-layer slides. PrepMate automatically mixes and removes specimens from the SurePath preservative fluid vials, and layers the specimens onto the SurePath density reagent in a test tube for automated slide preparation and staining. The PrepMate accessory is intended to reduce the time required to prepare samples for processing on the PrepStain instrument. The FDA approved the PrepMate accessory in May 2001.

In August 2004, we submitted new clinical data to the FDA in support of a supplemental filing to our PMAS for the PrepStain System to include approval of testing of cervical cells collected using the SurePath Test Pack for high-risk human papilloma virus (HPV) DNA with the Digene Corporation (Digene) hc2 High-Risk HPV DNA Test™. In the first quarter of 2005 we announced that we had withdrawn our pre-market approval supplement (PMAS) submission to the FDA to seek approval for expanded claims for the SurePath liquid-based Pap test to include an out-of-vial option for testing cervical cells collected using the SurePath Test Pack for the presence of high risk HPV DNA with the Digene hc2 High-Risk HPV DNA Test™. We resubmitted this PMAS, using new and existing data and data analyses in the fourth quarter of 2005. There can be no assurance that our re-submission will receive the required regulatory approvals, when anticipated, if at all.

FocalPoint Imaging System

Our *FocalPoint Imaging System* is a computerized imaging system that applies proprietary technology to screen SurePath or conventionally prepared Pap smear slides by identifying those slides that have the highest likelihood of abnormality. The FocalPoint Slide Profiler was approved by the FDA for primary screening of conventional Pap smears in May 1998 and for SurePath slides in October 2001. The FocalPoint GS Imaging System, which combines the automated sorting and ranking capability of the currently approved FocalPoint Slide Profiler with FocalPoint GS location-guided screening of areas of interest, was introduced outside of the U.S. in the fourth quarter of 2000.

Our *FocalPoint Slide Profiler* is an automated primary screening device that combines computerized video microscopy and image interpretation to distinguish between normal and abnormal SurePath liquid based and conventionally prepared Pap test slides. The FocalPoint Slide Profiler is intended to sort and rank slides based on the likelihood of abnormality, distinguish slides that need further cytotechnologist review from those that require 'No Further Review' (up to 25% least likely to be abnormal), and to identify slides in an enriched quality control population (a minimum of 15% of slides with a highest likelihood of being abnormal) for a directed quality control (QC) review. In addition, sorting, ranking, adequacy and other slide information provided by the FocalPoint Slide Profiler facilitates the manual microscopic review of slides designated for full microscopic review.

Our *FocalPoint GS Imaging System* (FocalPoint GS) combines the automated sorting and ranking capability of the FocalPoint Slide Profiler with a rapid screen of areas of interest, or Fields of View (FOV), on slides designated for review by the FocalPoint Slide Profiler. The FOV location coordinates and associated images are communicated via a network connection from the FocalPoint Slide Profiler to designated FocalPoint GS Review Stations that have been equipped with commercially available microscopes and computer-controlled automated stages for FOV review. FOV's determined by the FocalPoint GS to demonstrate the highest likelihood of abnormality are presented for a focused microscopic review that 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. In October 2004, we submitted clinical data to the FDA in support of a PMAS for the FocalPoint Slide Profiler to expand our claims to include approval of FocalPoint GS. In September 2005, we withdrew this PMAS having been notified by the FDA that the PMAS must be amended to include additional data. Based on subsequent feedback received from FDA, we expect to initiate collection of new data in support of a FocalPoint GS PMAS application in the first quarter of 2006 and we anticipate that we will complete the collection of new data in the first half of 2006 and submit our PMAS shortly thereafter. There can be no assurance that the FocalPoint GS system will receive the required regulatory approvals for sale in the United States, when anticipated, if at all. We currently market FocalPoint GS to certain markets outside the US.

Molecular Diagnostics Products

We expect to generate increasing revenues from the early commercialization of some of our molecular diagnostic products and molecular imaging systems in 2006 and believe that sales related to these developing products will significantly impact our growth in the future. The following table describes the stage of development of the product candidates in our molecular oncology pipeline and indicates what year we have released (marked by an asterisk) or expect to release the product in the indicated format. In the table, and elsewhere within this

document. "RUO" means "Research Use Only", "ASR" means "Analyte Specific Reagent", "IUO" means "Investigational Use Only", and "IVD" means "In Vitro Diagnostic".

Our Developing Molecular Oncology Pipeline

Application	Format	Release Date/ Estimated Target Date
Reagents		
Microscopic Slide Based		
Melanoma	ASR	2003*
Cervical Cancer	RUO	2004*
Breast Cancer	RUO	2004*
ProEx C	ASR	2005*
ProEx Br	ASR	2005*
Cervical Cancer Staging	Assay Kit (Outside U.S.)	2005*
SurePath Molecular Pap	IUO	2005*
Breast Cancer Staging	IUO	2005*
ProEx C	Class I IHC	2006
SurePath Molecular Pap	IVD Assay Kit (U.S.) in clinical trials	2007
Breast Cancer Staging	IVD Assay Kit (U.S.) in clinical trials	2007
Blood Based		
Ovarian Cancer	RUO	2005*
Breast Cancer	RUO	2007
Prostate Cancer	RUO	2008
Ovarian Cancer Screening	IVD Assay Kit	2008
Breast Cancer Screening	IVD Assay Kit	2009
Prostate Cancer Screening	IVD Assay Kit	2010
Reagent Enabling Products		
SureDetect General Purpose Reagents	U.S. (included in Outside U.S. kit)	2005*
SMS 3600 Automated Stainer	U.S. & Outside U.S.	2005*
Imaging Platforms		
Interactive Histology Imager	ER/PR 510(k)	2005*
	HER-2/Neu 510(k)	2005*
	Ki-67 510(k)	2006
	Additional "known" markers	2006
	Breast Staging IUO	2005*
	Other Applications	2006

While the dates provided above represent our estimated target dates for certain products, there can be no assurance that these targets will be achieved by the dates targeted, or ever. Further, there can be no assurance that FDA approvals necessary to reach our target dates for IVD format products will be achieved when we expect, if at all, or that any foreign regulatory approvals necessary for any foreign releases will be achieved when we expect, if at all.

Microscopic Slide Based Reagents

Our *ProEx C* ASR incorporates molecular biomarkers that measure the over-expression of proteins whose over-expression is associated with aberrant S phase induction, an abnormal growth state associated with the development of cancer. Aberrant S phase induction has been associated with cancer of the cervix, esophagus, ovary,

lung, and prostate. We are in the process of converting this ASR reagent to a Class I IHC product. Per FDA guidance documents, Class I IHC's are in-vitro diagnostic devices that provide a pathologist with adjunctive diagnostic information and are used after the primary diagnosis is made. Class I IHC's are subject to good manufacturing practice regulations, but are exempt from 510(k) pre-market notification. This Class I IHC labeling will enable us to provide additional instructions for use and assay performance information to our customers. However, there can be no assurance that we will be successful in obtaining the labeling that we desire.

Our *ProEx Br* ASRs incorporate molecular biomarkers that measure the over-expression of certain proteins that are believed to reflect increased activity in molecular pathways that are associated with the progression of cancer.

Our *Cervical Staging Assay* incorporates proprietary molecular biomarkers and reagents and is being developed to identify biopsy proven underlying pre-malignant cervical disease and cervical cancer in patients who have tested positive for high-risk human papilloma virus infection or for whom the results of cytologic screening with the SurePath liquid-based Pap test are equivocal or LSIL. We launched a cervical staging diagnostic kit outside the U.S. in 2005 having received the necessary international regulatory approvals. Concurrently, we released a detection kit for visualization of biomarkers on cytology slides, an automated cervical cytology slide-staining platform and a series of assay control reagents in 2005.

Our cervical screening assay, the *SurePath Molecular Pap*, incorporates proprietary molecular biomarkers and reagents and is being developed for primary screening for cervical cancer. The assay is being developed to test slides prepared using the SurePath liquid-based Pap test and to permit concurrent evaluation of morphologic features and measurement of the over-expression of molecular biomarkers that are associated with biopsy proven moderate to severe cervical disease and cancer. We initiated operational activities leading to clinical trials in 2005, with the trials having begun in early 2006, to collect data that could support an application for pre-market approval by the FDA. Given the relatively low prevalence of moderate to severe cervical disease and cervical cancer and the fact that the results obtained with our molecular biomarkers may dictate a need for additional follow-up of some clinical trial subjects over time, we believe that this clinical trial may require from 12 to 18 months to complete.

Our *Breast Cancer Staging Assay* incorporates proprietary molecular biomarkers and reagents and is being developed to predict the risk of disease recurrence and to aid in treatment selection in patients with early stage breast cancer. The assay is being developed for use with commercially available detection kits and staining platforms and to utilize our interactive histology imaging system (see below) to quantify biomarker over-expression in tissue samples collected at the time of initial diagnosis of breast cancer. We initiated trials in 2005 to collect data that could support an application to the FDA. We expect to submit these data to the FDA in the second half of 2006.

Over the past three years we have also released several RUO products, including microscopic slide based RUO reagents for staging of melanoma and cancer of the cervix and breast.

In data presented in 2004 from a study completed in 2003, investigators at Albany Medical College observed that the measurement of melastatin™ expression using our melanoma assay provided independent prognostic information that may be useful in determining the risk of disease recurrence and metastasis in patients with primary thin melanoma lesions. There can be no assurance that the results of these research and in-house studies will demonstrate the results that are the same as or are similar to the results we may obtain in any future studies or clinical trials.

We released our RUO reagents for cervical and breast cancer staging in 2004. Investigators at the Massachusetts General Hospital, Johns Hopkins Hospital, and the University of Colorado have evaluated the analytical and clinical performance of our RUO reagents for cervical cancer staging. In late 2005, we reported results of an in-house retrospective research study which demonstrated that testing of cervical cytology specimens with RUO reagents incorporating our ProEx C biomarkers yielded a 93% ($p<0.0001$) improvement in sensitivity for detection of biopsy evidence of high grade cervical intraepithelial neoplasia (CIN2+) when compared to a high grade abnormal cytology classification of HSIL+. The results of this retrospective research study also demonstrated a 65% improvement in calculated Positive Predictive Value for detection of CIN2+ when compared to all atypical and abnormal cytology classifications combined, defined as ASCUS and higher (ASCUS+). In addition to this in-house study, six additional studies were presented at the November 2005 meeting of the American Society of

CytoPathology (ASC). Investigators from the Johns Hopkins Medical Institutions and the University of Colorado reported virtually no variability with regard to scoring and staining reproducibility when using a "home brew" version of the ProEx C ASR. These researchers further concluded that their "home brew" assays were unaffected by routine laboratory environment factors in these studies. In a separate study, investigators from Johns Hopkins Medical Institutions observed that testing with the ProEx C biomarkers may assist with the detection of cytologic abnormalities on microscopic examination.

Investigators at Albany Medical College reported in December 2005 that data from a research study conducted there using our ProEx Br biomarkers demonstrate a strong correlation between biomarker reactivity and the risk of disease recurrence within five years from initial diagnosis of early stage breast cancer.

There can be no assurance that the microscopic slide based reagents that we are developing will be ready to launch or receive required regulatory approvals when anticipated, if at all.

Blood-Based Reagents

We have initiated development of blood-based screening and monitoring assays for ovarian and breast cancer. As mentioned in the table above, we released our ovarian ELISA-formatted RUO reagents in 2005 and anticipate releasing our breast screening reagents in RUO formats during 2007 and prostate screening reagents in RUO formats in 2008. We also anticipate the release of other blood-based reagents after 2007 as discussed in the table above. Concurrent with the development of these reagents we are evaluating multiplex testing platforms that will allow for simultaneous testing of multiple markers from a small volume of blood.

Reagent Enabling Products

We released the SureDetect general purpose reagents in 2005. These are general purpose reagents that are intended for use with both manual and automated immunocytochemistry and immunohistochemistry staining procedures. We released the SMA 3600 molecular stainer in 2005 as well. It is an open and automated slide staining platform that is compatible with immunocytochemistry and immunohistochemistry reagent applications.

Molecular Imaging Systems

Our *Interactive Histology Imaging System* allows rapid, reliable and cost effective quantification of molecular biomarkers in histologic tissue sections. This product provides on-demand digital imaging, direct visualization of immuno-histochemistry (IHC) stained slides, and real-time quantitative analysis of tissue samples. Ventana Medical Systems, Inc. (Ventana) sells and distributes a Ventana-branded version of our interactive histology imaging system, the Ventana Image Analysis System (VIAS) under a five-year global supply agreement that we entered into in September of 2004. Ventana launched VIAS in the second quarter of 2005 after we received 510(k) clearance from the FDA for processing Ventana estrogen and progesterone receptor assays on the system. In the third quarter of 2005, we received clearance of a 510(K) notification from the FDA for the VIAS when used with tissues stained for HER-2/neu. Ventana also revised their product labeling and received FDA clearance for processing their HER-2/neu reagents on VIAS during the third quarter of 2005. In the fourth quarter of 2005 we submitted a 510(k) notification requesting clearance for processing of Ventana's Ki67 reagent on the VIAS platform. We anticipate filing additional 510(k) notifications for processing of other Ventana assays in 2006 and beyond. There can be no assurance that we will obtain the desired, future FDA clearances when anticipated, if at all, nor that Ventana will prioritize the marketing of VIAS.

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 2002 exceeded 10.5 million cases, excluding basal and squamous cell cancers of the skin. The WHO further estimates that approximately 6.72 million deaths worldwide were attributable to cancer in 2002. In the United States, the American Cancer Society (ACS) estimates that roughly 1.4 million cases of non-skin cancers will be diagnosed in 2006, roughly half of which will occur in women. In the United States, women have about a 1-in-3 lifetime risk of developing invasive cancer. It is estimated that in 2006 approximately 680,000 women will be newly diagnosed

with cancer and an estimated 274,000 women will succumb to the disease. It is anticipated that melanoma and cancers of the breast, cervix, and ovary will account for approximately 40% of all new cancers diagnosed in women in 2006.

Women's Cancers
2006 Cancer Estimates (U.S.)

	Estimated 2006 Incidence	Estimated 2006 Mortality
All Cancers	679,510	273,560
TriPath Imaging Targeted Cancers:		
Breast	212,920	40,970
Ovarian	20,180	15,310
Malignant Melanoma	27,930	2,890
Cervical	9,710	3,700

Source: American Cancer Society, Facts & Figures, 2006

Treatments for cancer are expensive and often ineffective. Current treatments for cancer include surgery, radiation, chemotherapy and targeted therapeutics. 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 projects that in 2006 over 273,000 women will die 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 for the period 1995-2001:

Five Year Disease — Free Survival
by Stage at Diagnosis

TriPath Imaging Targeted Cancers:	Localized Disease (%)	Regional Spread (%)	Distant Metastases (%)
Breast	98	80	26
Ovarian	94	69	29
Malignant Melanoma	98	60	16
Cervical	92	53	17

Source: American Cancer Society, Facts & Figures, 2006

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 64%, the relative survival rate for currently screened cancers (i.e. including cancers of the cervix, breast, rectum and skin) is approximately 84%. The 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. The National Institutes of Health estimates the overall costs for cancer-related illness in the U.S. was $209.9 billion for 2005.

We expect the market for cancer diagnostics will 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 is likely to be as important as understanding the underlying cause of the genetic change itself. The scientific community's knowledge of these underlying genetic and proteomic 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 and proteomic 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 in women worldwide. According to the WHO the worldwide incidence of cervical cancer in 2002 was 493,243 with a mortality rate of 273,505. In parts of the developing world, cervical cancer is the major cause of death in women of reproductive age. The ACS estimates that in 2006 approximately 9,710 cases of invasive cervical cancer will be diagnosed in the U.S. with an estimated 3,700 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.

Screening for Cervical Cancer

Based on the concept that the physical appearance (or morphology) of cells that have been scraped from the surface of the uterine cervix may correlate with and, therefore, signify the presence of cancer or its precursors in underlying cervical tissue, the Pap smear has been employed worldwide as a primary screen for cervical cancer and its precursors since the late 1940's. It is the most widely used and most successful of all screening tests for cancer having contributed to a greater than 70% decrease in deaths resulting from cervical cancer in the U.S. since it was first introduced. It is estimated that clinical laboratories in the United States perform over 50 million Pap tests, including liquid based Pap tests, annually and we believe that the annual test volume outside of the United States is in excess of 80 million.

The Pap smear, as first developed by Dr. George N. Papanicolaou in the 1940s, remained essentially unchanged until the introduction of liquid based Pap tests, such as our SurePath liquid based Pap test, in the 1990s. The liquid based Pap test was developed to remedy several practical limitations of the conventional Pap smear, including those related to specimen collection and slide interpretation. The use of a liquid medium to transport cervical cells may facilitate the specimen collection process by reducing the time taken to prepare the specimen for transport, by eliminating air drying and other collection related artifacts that distort cell architecture, by providing a readily accessible medium and adequate shelf life to allow for repeat testing from the original sample, by providing a readily accessible medium for potential adjunctive testing for infectious, genetic or other diseases and, in the case of our SurePath liquid based Pap test, by providing a standardized technique for specimen collection that ensures that all cells collected are transported to the laboratory. The thin layer slides prepared using liquid based Pap tests eliminate the depth of focus issues that may complicate the interpretation of the relatively thick conventional Pap smear and are relatively devoid of blood, mucus, or inflammatory material that may obscure significant cytologic pathology. In the case of our SurePath liquid-based Pap test, the combination of these collection and slide preparation features contributes to a statistically significant reduction in the number of unsatisfactory cases when compared to the conventional Pap smear.

The Pap smear is prepared from scrapings of the surface of the uterine cervix that are collected during a gynecologic pelvic examination. These exfoliated cervical cells are, in the case of the conventional Pap smear, directly transferred to a glass slide by the clinician who collects the specimen. In the case of the liquid based Pap test, such as our SurePath liquid based Pap test, these exfoliated cells are transferred by the clinician into a liquid medium from which a thin layer slide is subsequently prepared in the laboratory, most often using an automated system such as our PrepStain slide processor, after the liquid medium, blood, mucus, and other obscuring materials are removed by density gradient centrifugation. With the conventional Pap smear, the clinician discards the collection device and whatever cells that remain attached to the device, after the sample is transferred to the glass slide. With the SurePath liquid based Pap test, the clinician simply detaches the head of the collection device and places it into the liquid transport medium, thus, ensuring that 100% of the cells that have been collected are transported to the laboratory. For either the conventional or liquid based Pap tests, a Papanicolaou stain is applied to the slide to facilitate microscopic review. The slide is then analyzed microscopically by a cytotechnologist who evaluates the appearance of the ex-foliated cells. The cytotechnologist looks for cell features that are associated with cancer of the cervix or its precursors. Any abnormality so detected is further reviewed by a pathologist. Depending on the cytologic classification that has been assigned by the pathologist, abnormalities that are confirmed by pathologist review are further evaluated by testing for human papilloma virus (HPV) and/or direct visual examination of the cervix using a colposcope and, if a lesion is so detected, a biopsy to obtain cervical tissue for histologic examination. Biopsied cervical tissue is evaluated for histologic evidence of the loss of uniformity of individual cells, the loss of architectural orientation, and other abnormal findings that are associated with Cervical Intraepithelial Neoplasia (CIN) and cervical cancer. CIN, which is also referred to as dysplasia, is characterized by pre-cancerous changes in cervical tissue, and is further categorized into CIN 1, CIN 2, or CIN 3 (mild, moderate, and severe dysplasia) depending on the severity of abnormality. Further treatment or follow-up is dictated by the results of the cervical biopsy and most often follows consensus guidelines that have been developed by opinion leaders in concert with various clinical organizations and advocacy groups.

Typically, about 90% to 95% of all Pap smears are classified as normal. Abnormal Pap smears are classified in order to specify the degree of cytologic abnormality, according to The Bethesda System (2001). The prevalence of histologic evidence of CIN and cancer varies with each cytologic classification. For example, the cytologic classification of atypical squamous cells of undetermined significance (ASC-US) represents the least significant cytologic abnormality and is associated with only a relatively small number of biopsies that demonstrate underlying premalignant or malignant cervical disease. Low-grade squamous intraepithelial lesion (LSIL) is associated with a slightly higher likelihood of underlying disease, particularly CIN 1 and, most often, appears to reflect cytologic changes that are associated with HPV infection. Atypical squamous cells of undetermined significance-cannot exclude high grade (ASC-H), a recently introduced classification, is associated with a somewhat higher number of biopsies that demonstrate CIN 2 or more severe disease. High-grade squamous intraepithelial lesion (HSIL), is a very significant cytologic abnormality that is associated with a very high correlation to biopsy evidence of CIN 2, CIN 3, and, not infrequently, cancer. The most significant cytologic classification is cancer itself where the correlation to biopsy evidence of cancer or severe dysplasia is very strong.

Human Papillomavirus

Since the mid-1970's, Human Papillomavirus, or HPV, has been recognized as a sexually transmitted infection that is associated with the development of genital tract neoplasia. Of the approximately 70 types of HPV viruses recognized to date, more than 20 have been associated with lesions in the female anogenital tract. The so-called low risk types (i.e. 6, 11, 42, 43 and 44) are mainly associated with benign lesions such as condylomas, which rarely progress to malignancy. The so-called high-risk types (i.e., 16,18,31,33,35,39,45,51,52,56 and 58) are detected in cancer of the cervix.

While it has been documented that nearly all cervical cancers (99.7%) are directly linked to previous infection with one or more of the high-risk types of HPV (Judson 1992; Walboomers et. al. 1999), infection with HPV, even a high-risk type, in and of itself is not diagnostic of cervical cancer or its precursors. Most HPV infections are transient and are not associated with the development of cervical cancer or its precursors. Given the biology of the infection and its association with cervical neoplasia, if one were to test for high-risk HPV (even with a test that is 100% sensitive and specific for high-risk HPV) one would expect that the negative predictive value for testing for

high-risk HPV, that is the likelihood that a negative test for high-risk HPV is associated with absence of CIN 2 or more severe cervical disease, would approach almost 100%. However, one would also expect that the positive predictive value of a test for high-risk HPV, that is the likelihood that a positive test for high-risk HPV is associated with the presence of CIN 2 or more severe lesions, would range from 10 to 25% depending on the age of the population tested. A negative HPV test effectively rules out the presence of CIN 2 or more severe cervical disease, whereas, a positive HPV test indicates the presence of a risk factor that may or may not lead to the future development of CIN 2 or more severe cervical disease.

Over the past few years, testing for infection with high-risk types of HPV has gained clinical acceptance in the U.S. in certain clinical situations. The 2001 Consensus Guidelines sponsored by the American Society for Colposcopy and Cervical Pathology (ASCCP) recommend testing for HPV to assist in the management of women with ASCUS-US Pap test results. These guidelines are supported by a number of studies including the NCI-sponsored *ASCUS/LSIL Triage Study for Cervical Cancer (ALTS)* trial that demonstrated that HPV testing within the ASC-US patient population was an effective method of triaging these patients for subsequent referral to colposcopy because of the extremely low likelihood of finding cancer or its precursors in the absence of infection with high-risk HPV. The Guidelines recommend that patients with ASC-US who test negative for high-risk HPV should be managed by follow-up Pap smear and HPV testing and that patients with ASC-US who test positive for high-risk HPV should be immediately referred for colposcopy and possible biopsy. In the ALTS trial, the positive predictive value (PPV) of HPV testing within the ASC-US patient population, however, was shown to be only 17%.

In March 2003, the FDA approved a submission by Digene Corporation to include HPV as an adjunct to the Pap smear for primary screening for cervical cancer in women age 30 and older. The rationale for this approach is predicated on the extremely low likelihood of finding cancer or its precursors in the absence of high-risk HPV infection when the Pap smear is normal. In fact, the negative predictive value of the two tests in combination is greater than 99%. However, the lack of specificity and relatively low positive predictive value of HPV may again be problematic. For example, approximately 2% to 6% of women with normal Pap smears yield positive tests for high-risk HPV. The management of such patients is as yet unclear. Furthermore, although approximately 56% of patients with ASC-US and 85% of patients with LSIL test positive for high-risk HPV, the rate of detection of CIN 2 or more severe lesions on biopsy in these populations is only 10% and 20% respectively.

Two major pharmaceutical companies are currently developing experimental vaccines designed to protect against several of the oncogenic and non-oncogenic strains of HPV. These vaccines target particular variants of HPV that are linked to cervical cancer, and both vaccines have shown significant efficacy in trials.

Experts have noted significant potential medical limitations to these vaccines, if approved: (i) they offer no protection against types of HPV not targeted by the vaccines; (ii) it is unknown whether boosters will be necessary nor whether the "selective pressure" of potential eradication of the HPV will lead to the predominance of other oncogenic strains of HPV that are currently less common; and (iii) these vaccines do not prevent HPV infections from progressing to cancer if the infections are already present at the time of vaccination. There also may be social and economic hurdles to introducing HPV vaccines on a large scale.

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 ACS estimates that in 2006, approximately 212,920 new cases of invasive breast cancer will be diagnosed among women in the United States, with an estimated 40,970 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 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 (98%), regional spread (80%) and distant metastases (26%).

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 current 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 four 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. (HCA Cancer Care, November 2002. Informational Guide to Breast Cancer).

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 breast 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 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.

Breast Cancer 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, but it is among the most deadly. In 2002, 204,499 new cases were diagnosed and 124,860 deaths were reported worldwide (WHO). In 2005, the American Cancer Society (ACS) reported 22,220 new ovarian cancer cases in the U.S. and 16,210 deaths from the disease. The five-year relative survival rate for all women diagnosed with ovarian cancer is 53%; however, survival rates vary by stage of disease. For example, the ACS reports an estimated 94% five-year survival rate for localized ovarian cancer, but only 69% if the cancer has spread regionally, and only 29% 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 currently available modalities, including CA-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 pelvic examination, transvaginal ultrasound and/or CA-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 have a surgical procedure to rule out and/or diagnose ovarian cancer. Typically, 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.

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 2002, the WHO estimated that 81,134 cases of melanoma were diagnosed in women and 18,829 female deaths were attributable to this deadly disease. The ACS estimated that in 2005, 26,000 women in the U.S. would be diagnosed with melanoma and 2,860 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 99%. Survival rates drop considerably to 60% and 16% 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, nodal involvement and distant metastasis, or the TNM classification system discussed above. 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 five years. As with other types of cancer, 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 judgment.

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 a promising approach for the prognostic assessment of thin melanoma lesions.

Marketing and Sales

Marketing Strategy

Our marketing strategy is focused on providing solutions that address the unmet needs of our three broad market stakeholders: clinical laboratories, clinicians, and third-party payors. We increased our marketing efforts during the first half of 2004 by directing resources toward various marketing-related initiatives designed to promote brand identification and awareness within the target segments to increase market acceptance of our products and services. We have expanded our presence in the marketplace through increased advertising and promotion, company-sponsored symposia, trade shows, and direct selling activities. In September 2004, we initiated an expansion of the sales force to leverage the opportunity created by our growing relationship with the large commercial laboratories (see below) and to meet the challenge associated with expanding our cervical cytology business in this heavily contested market segment while maintaining and growing our business within our traditional customer base.

Clinician/OB-GYN

Over the past several years we have expanded our clinician educational programs to better focus on this large segment. We also conducted 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. Finally, we cultivated and developed 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 increased 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.

Cervical Cytology Product Line

We currently market our cervical cytology products as part of an integrated system. Our SurePath, PrepStain and FocalPoint systems, together, provide an integrated solution for sample preparation, processing, staining and computerized analysis of liquid based thin-layer slide 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 and FocalPoint GS systems, in 1995 and of the FocalPoint primary screening system in 1998. FocalPoint is the only fully automated Pap smear screening device to receive regulatory approval 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 payors in connection with screening for cervical cancer. In an effort to facilitate the adoption of our products, we engaged 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 payor/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 also includes 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 commercial laboratories. Pap 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 productivity over manual 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. We believe that the large clinical laboratories continue to offer a significant opportunity for our growth in 2006 as we have entered into agreements and have established growing relationships with the three largest commercial laboratories in the U.S.

In the first quarter of 2003, we entered into an agreement with Quest Diagnostics Incorporated (Quest Diagnostics or Quest) to introduce our cervical cancer screening products in select locations. Quest Diagnostics completed an evaluation process of these products in late 2003. Early in the second quarter of 2004, on the strength of the outcome of this evaluation, we entered into a new multi-year agreement with Quest Diagnostics. Under this agreement, Quest Diagnostics is adopting the SurePath liquid-based Pap test and the PrepStain system and is evaluating the FocalPoint Slide Profiler. During the term of the agreement, we will work together with Quest Diagnostics to expand the use of our products by educating physicians about the benefits of our technology. We also renewed a multi-year agreement with Laboratory Corporation of America in the latter half of 2003 and entered into a new multi-year agreement with LabOne in mid-year 2004. LabOne was subsequently acquired by Quest Diagnostics. LabOne has since fallen under the provisions of the agreement we have with Quest Diagnostics.

In September of 2004, we initiated an expansion of our sales and marketing activities in the U.S., to leverage our growing relationship with the large commercial laboratories and to meet the challenge of expanding our cervical cytology business in this highly competitive segment while growing and maintaining our business within our traditional customer base. We have reorganized our sales management to ensure accountability and support for a larger field sales organization and to ensure broad geographic coverage. We completed expansion of our sales management team in the fourth quarter of 2004 and continued the expansion of our field sales organization over 2005. In addition, we expect to make increased investments in marketing and sales related activities in support of our current cytology products worldwide as well as to begin to prepare the market for the future introduction of our molecular oncology products. There can be no assurance that our agreement with Quest, or other large laboratory customers, will continue to generate significant revenue.

Academic Centers of Excellence. We expect to maintain and 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 payor. This is of particular significance to our strategy for commercializing molecular diagnostic products 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 represents a promising opportunity for our equipment rental programs.

Third-party payors. We have gained a significant level of market acceptance for our products by third-party payors 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 payors. 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 prostate. 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 payors will reflect the extent to which the products positively impact patient outcome, both clinical and economic. Fourth, we employ a strategy for early commercialization that includes initial introduction of ASRs to be used in laboratory-developed assays. Fifth, we intend to leverage the recognition, relationships, and infrastructure developed to market and sell our cervical cytology product line to commercialize our molecular diagnostic products. In effect, we expect the infrastructure we have developed for our cervical cytology product line to serve as a conduit for our molecular diagnostic products.

In September 2004, we entered into a five-year global supply agreement with Ventana under which Ventana obtained exclusive rights to sell and distribute worldwide a Ventana-branded version of our interactive histology imaging system that we are developing to be optimized for both Ventana and TriPath Imaging assays. The interactive histology imaging system was developed to offer anatomic pathology laboratories a cost-effective solution utilizing on-demand digital imaging, direct visualization of IHC stained slides, and real-time quantitative analysis of tissue samples. We believe that in addition to non-recurring revenue already recorded, the agreement provides the potential for capital equipment and fee-per-use revenues in 2006 and beyond. We submitted a 510(k) notification and received marketing clearance from the U.S. Food and Drug Administration (FDA) for processing Ventana estrogen and progesterone receptors and HER-2/neu assays on the system. We submitted a 510(k) notification for processing Ventana's Ki67 assay in the fourth quarter of 2005 and anticipate filing additional 510(k) submissions in 2006.

Sales Strategy

Cervical Cytology Product Line

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 is the predominant vehicle for international instrument sales. If, however, we sell an instrument directly to an international end user, we record the revenue upon installation and acceptance of the instrument, consistent with our treatment 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, revenue recognition occurs at the time of shipment of the reagent kits or on a monthly basis based on the actual or minimum usage. There is no capital equipment revenue recognized under these transactions. However, we retain ownership of systems placed under these various rental agreements.

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 respond to customer needs by offering both capital and operating lease alternatives. Under the capital lease alternative, revenue is recognized initially as an instrument sale with part of the lease payments being allocated to interest income, and service revenues, if applicable, over the lease term. Under operating leases, we do not recognize any revenue related to the instrument sale, but recognize revenue as rental income over the lease term. We retain ownership of systems placed under operating leases.

We also generate revenue from the sale and 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.

Molecular Diagnostic Reagents and Imaging Systems

We introduced some of our molecular diagnostic reagents and imaging systems in 2005 (see "Molecular Diagnostic Products" under "Our Products" above). We introduced our ProEx C and ProEx Br ASRs (see Government Regulation) to early adopters among academic centers, hospital laboratories, and independent clinical laboratories in the U.S. through our existing laboratory sales organization. It is the responsibility of the laboratory that purchases the ASR to develop an in-house assay, validate assay performance, and promote the assay. We also introduced our cervical and breast staging assays outside the U.S. during 2005. Our interactive histology imaging system was launched by Ventana pursuant to our five-year global supply agreement under which Ventana obtained exclusive rights to sell and distribute worldwide a Ventana-branded version of the system. We believe the agreement provides the potential for capital equipment and fee-per-use revenues in 2006 and beyond.

Marketing and Sales Organizations

We employ more than 150 full-time marketing and sales personnel worldwide to market, sell and provide post-sale support of our products, in addition to leveraging distributor networks in our markets outside the U.S., with the exception of Canada, where we sell through our own sales and marketing organization. We have begun selling into certain non-Canadian international markets directly to end-user customers, but our predominant mode of selling internationally is still through distributors. In addition to expanding our existing cervical cytology business our intention is to leverage our sales and marketing capabilities, our strong relationships with key influential leaders in the anatomic pathology laboratory and clinician segments, and our customer base among the academic institutions to accelerate the adoption of molecular-based reagents for laboratory developed assays in 2006 and beyond.

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. In September 2004, we initiated an expansion of our sales and marketing activities in the U.S., targeted primarily toward our pursuit of additional business under our agreements with large commercial laboratories. We believe our sales management is structured to ensure accountability and support for a larger field sales organization and to ensure broad geographic coverage. We completed expansion of our sales management team in the fourth quarter of 2004 and completed the expansion of our field sales organization during 2005, and we hired a new Vice President, Marketing in late 2005. We also employ field-based reimbursement specialists who call on U.S. managed care organizations and other third-party payors to achieve maximum reimbursement levels and to further stimulate demand for our products. Where, and if, 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 12 full-time personnel, consisting of a sales director, and a sales, marketing and service staff located in Europe. We anticipate expanding our international sales and service team in 2006 to meet the requirements of our growing international business. 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 participated in a product evaluation in the U.K. related to liquid-based cytology testing for cervical cancer. In October 2003 the National Institute for Clinical Excellence ("NICE," or the "Committee") in the U.K. issued guidance that recommends the adoption of liquid-based cytology for cervical cancer screening. The formal guidance recommends that liquid-based cytology be used as the primary means of processing cervical cancer screening samples in England and Wales. We have been awarded contracts for cumulative commitments of over 36% of the market in the U.K., 39% in England and Wales to supply our SurePath liquid-based Pap test. The

United Kingdom National Health Service, which plans to convert completely to liquid-based cytology, represents growth potential for our products. We are currently participating in a U.K. evaluation of screening of liquid based slides using the FocalPoint GS Imaging system.

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

Manufacturing

SurePath and PrepStain

We currently assemble, test and package components of PrepStain, and its accessory, PrepMate 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 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.

The consumable items used with PrepStain are purchased from a variety of third-party vendors, some of which are sole-source suppliers. In December 2004 we completed a multi-year, exclusive contract with a European supplier of manufactured instrument components that are incorporated into our PrepStain product line. Those instrument components are now purchased from a U.S. subsidiary of that European supplier. We have successfully supplied PrepStain market requirements utilizing this U.S. subsidiary during 2005. Service parts may continue to be purchased from the European supplier. Pricing for components is fixed, but is subject to adjustment based upon changes in raw material costs. We believe that our supplier has sufficient capacity to meet our present and future requirements for these components. We believe our supplier will allow us to ensure an uninterrupted supply of PrepStain component parts.

FocalPoint

We currently assemble, integrate and test the FocalPoint electronic, mechanical and optical components and modules 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 product.

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.

Molecular Diagnostics Reagents

In 2004, we began in-house manufacturing of molecular diagnostic reagents that were developed for commercialization at our TriPath Oncology facility. Our molecular diagnostic manufacturing is performed in a dedicated suite built at our Burlington, North Carolina facility. Molecular reagent products consist of monoclonal antibodies grown and purified in house, diluted, filled, labeled and packaged for their commercial release which began in 2005. We believe we have sufficient manufacturing expertise and capacity to meet anticipated near-term customer demand for our molecular diagnostic product line.

Imaging Systems

In 2004, we began manufacturing our new Interactive Histology Imaging System in Burlington, North Carolina, in support of our exclusive sales and distribution agreement with Ventana. Our Interactive Histology Imaging System, VIAS, consists 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 also began manufacture of our Molecular Cytology Imaging System in our Burlington, North Carolina facility in 2005. We believe we have sufficient capacity to meet anticipated customer demand for our molecular imaging product line.

We also manufacture a limited number of our GS Review Stations and integrate them into the FocalPoint GS for international sales at our Redmond, Washington facility. Our GS Review Stations 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. We believe we have sufficient capacity to meet anticipated near-term customer demand for our SlideWizard product line.

Lean Manufacturing Strategy

Since 2002 we have applied the principles of Lean Manufacturing in our organization. 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, One-Piece Flow, Kanban Materials Management and Kaizen implementation methodology. During 2005, value stream driven Kaizen events continued, at a rate of at least one per month. We believe these efforts continuously serve to remove waste and inefficiencies from our manufacturing processes, resulting in lower costs, improved quality and delivery to our customers.

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 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, including 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 our 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 13485 certification, and Canadian and European regulatory requirements. A European "CE" certification is required to successfully sell PrepStain and FocalPoint in the European Economic Area (EEA, the 25 European Union member states, plus Norway, Iceland and Liechtenstein) according to certain European Community (EC) directives. The OEM supplier of the PrepStain instrument components has ISO 13485 certification and has obtained CE certification for the main PrepStain component. In December 2003, we met the essential requirements of the European In Vitro Diagnostic Medical Devices Directive (IVDD), which allowed us to add the CE Mark to our cytology products, and we have applied the CE mark to the entire PrepStain and FocalPoint systems.

We obtained ISO 13485:1996 certification at our Burlington, North Carolina facility in 1999. We obtained ISO 13485 certification at our Redmond facility in July 2003. Compliance audits have been routinely conducted at both our Burlington, North Carolina and Redmond, Washington facilities by certified ISO auditors, most recently in

December 2005 in Burlington and August 2005 in Redmond. During the December 2005 ISO audit in Burlington, the facility successfully upgraded the certificate to ISO 13485:2003. We have no outstanding deficiencies related to these compliance audits. In addition, the Burlington and Redmond manufacturing facilities successfully underwent ISO 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 13485 or 13488 and Regulation SOR/980282, as amended, is required and was obtained.

Research and Development (dollar amounts in thousands)

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

- development of molecular diagnostic products for malignant melanoma and cancer of the cervix, breast, ovary, and prostate,
- continued improvement of the FocalPoint Imaging System, PrepStain System and reagents and disposables,
- development of molecular imaging systems.

As of December 31, 2005, we had approximately 70 employees engaged in research and development activities. Our expenditures for research and development were $12,352, $11,280 and $8,861 for the years ended December 31, 2005, 2004 and 2003, respectively. See additional discussion in Item 7 — "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Development of Molecular Diagnostic Products

On July 31, 2001 we entered into a series of agreements with Becton, Dickinson and Company (BD) to develop and commercialize molecular diagnostic products for melanoma and cancer of the cervix, breast, ovary and prostate using genomic and proteomic markers identified at Millennium Pharmaceuticals, Inc. (Millennium). The products we are developing incorporate genomic and proteomic markers that were identified through discovery research conducted at Millennium under its research and development agreement with BD as well as other markers that have been or may be identified independently of that agreement. In January 2004, the molecular marker discovery process and transfer of all markers from Millennium was completed. We have used, and intend to use, these markers and related intellectual property to develop and commercialize tests and other products for these cancers. We will share commercial responsibilities with BD for any products that we have developed and will ultimately develop utilizing the markers developed pursuant to our research and development agreement with BD.

Five key components of our product development strategy are responsible for what we believe are the differentiating features of our molecular diagnostic products:

1) Our biomarker discovery process was outcome driven. We identified and validated our molecular biomarkers based upon predetermined clinical specifications and correlated the presence of specific molecular biomarkers with a series of clinical specifications for each of our targeted cancers. These clinical specifications are based upon unmet clinical needs and what we perceive to be a significant commercial opportunity.

2) Given the biological and clinical complexity of cancer it is generally accepted that cancer onset and progression are driven by multiple gene-related changes. As a result, with the exception of our RUO reagents for melanoma, each of our molecular assays incorporates multiple molecular biomarkers.

3) We believe that, if properly selected, a finite number of molecular biomarkers will yield molecular profiles, or signatures, that are correlative with clinical phenotype and patient outcome, thereby, limiting the complexity of testing technology and information management that is required by the performing laboratory. With the exception of our RUO reagents for melanoma, we expect our molecular products to incorporate up to ten molecular biomarkers per assay.

4) Our assay technologies are being developed in commercially accepted formats to facilitate rapid laboratory adoption. For our slide-based assays, we have chosen a standard IHC or immunocytochemistry (ICC) format with standard colorometric bright field detection to facilitate the quantification of molecular markers (proteins) within the context of cellular morphology. For our blood-based screening assays, we have

chosen an immunoassay format that is capable of detecting and quantifying multiple secreted proteins in blood. This approach requires us to generate monoclonal antibodies targeted to each unique protein that we wish to quantify. We do this by first translating the unique gene sequences identified by Millennium under its research and development agreement with BD, as well as other sequences that have been or may be identified independently of that agreement, into proteins using a number of protein expression systems and then develop 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.

5) We believe that the results obtained with molecular biomarkers in slide-based assays will be interpreted, at least initially, in the context of historical standards of practice, such as morphology. Given that tissue architecture, cell morphology, and precise sub-cellular localization of molecular biomarkers will be an important tool for accurate cancer staging and prognosis, we have adapted our proprietary image analysis platform to allow analysis and quantification of multiple, discrete molecular markers within the context of tissue distribution and cellular location. We also 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.

Over the past three years we have released several of our molecular diagnostic reagents in a RUO format to facilitate external research studies by independent investigators. We released RUO reagents for cervical and breast cancer staging in 2004 and for ovarian cancer in 2005. Investigators at the Massachusetts General Hospital, Johns Hopkins Hospital, and the University of Colorado have evaluated the analytical and clinical performance of our RUO reagents for cervical cancer staging. Investigators at Albany Medical College have evaluated the clinical performance of our RUO reagents for breast cancer staging.

In late 2005, we reported results of an in-house retrospective research study which demonstrated that testing of cervical cytology specimens with RUO reagents incorporating our ProEx C biomarkers yielded a 93% ($p<0.0001$) improvement in sensitivity for detection of biopsy evidence of high grade cervical intraepithelial neoplasia (CIN2+) when compared to a high grade abnormal cytology classification of HSIL+. The results of this retrospective research study also demonstrated a 65% improvement in calculated Positive Predictive Value for detection of CIN2+ when compared to all atypical and abnormal cytology classifications combined, defined as ASCUS and higher (ASCUS+). In addition to this in-house study, six additional studies were presented at the November 2005 meeting of the American Society of CytoPathology (ASC). Investigators from the Johns Hopkins Medical Institutions and the University of Colorado reported virtually no variability with regard to scoring and staining reproducibility when using a "home brew" version of the ProEx C ASR. These researchers further concluded that their "home brew" assays were unaffected by routine laboratory environment factors in these studies. In a separate study, investigators from Johns Hopkins Medical Institutions observed that testing with the ProEx C biomarkers may assist with the detection of cytologic abnormalities on microscopic examination.

Investigators at Albany Medical College reported in December 2005 that data from a research study conducted there using our ProEx Br biomarkers demonstrate a strong correlation between biomarker reactivity and the risk of disease recurrence within five years from initial diagnosis of early stage breast cancer. This research study included 217 archived breast tissue specimens from a retrospective cohort of patients with early stage breast cancer who had been followed for a minimum of five years following initial diagnosis. The research study included quantitative image analysis of the ProEx Br biomarkers utilizing an early version of the VIAS. In this retrospective study of archived breast tissue samples from patients with early stage breast cancer, researchers from Albany Medical College reported that the rate of breast cancer recurrence within five years of initial diagnosis was approximately 30% when archived breast tissue tested negative for all ProEx Br biomarkers and approximately 40% when positive for one or fewer ProEx Br biomarkers. When the archived breast tissue tested positive for two or more of the five ProEx Br biomarkers included in this research study, the rate of recurrence increased to up to approximately 70%. Multivariant Cox proportional analysis (Hazard Ratio) of the data collected in this study indicated a two-fold increase in the calculated risk of breast cancer recurrence within five years from initial diagnosis when testing with two or more of the ProEx biomarkers was positive (p value = 0.0141) as compared to the calculated risk of recurrence when testing was negative for all ProEx Br biomarkers. In their presentation, the researchers concluded that the ProEx Br biomarkers provided independent prognostic information regarding recurrence of breast cancer

and that these data support the potential utility of the ProEx Br biomarkers to risk stratify early stage, lymph node negative breast cancer patients. The results of this study were presented at the 28th Annual San Antonio Breast Cancer Symposium held in San Antonio, Texas.

In data presented in 2004 from a study completed in 2003, investigators at Albany Medical College observed that the measurement of melastatin™ expression using our melanoma assay provided independent prognostic information that may be useful in determining the risk of disease recurrence and metastasis in patients with primary thin melanoma lesions.

There can be no assurance that any future studies or clinical trials will yield results that are the same as or similar to the results of these research studies.

Improvement of FocalPoint Imaging System, PrepStain System, Reagents and Disposables

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 are also continuing to explore alternative uses for adjunctive testing using our SurePath preservative fluid.

Development of Molecular Imaging Systems

We are leveraging our extensive intellectual property portfolio, know-how, and experience in image analysis to develop molecular imaging systems that we believe will enhance the performance of our molecular diagnostic products. Our new interactive histology imaging system is designed to allow fast, reliable and cost effective quantification of different breast cancer markers applied to histological sections.

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, be successfully commercialized or demonstrate results that are the same as or are similar to our other early studies. The failure of any such enhancement or project to be completed, approved or commercialized could prevent us from successfully competing in our targeted markets.

Third-Party Reimbursement

Cervical Cytology Product Line

The vast majority of private third-party medical insurance providers and governmental agencies offer coverage and 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 payors for wellness testing, including the Pap smear can vary considerably. However, on average, since the majority of third party payors benchmark coverage and pricing based on Medicare coverage and reimbursement determinations, there has been a general increase in reimbursement amounts paid for cervical cancer screening due to a minimum payment of $14.76 established in 2002 by the Center for Medicare and Medicaid Services (CMS) which administers Medicare. In addition to the minimum established by CMS, subsequent Medicare National Limitation Amount (NLA) pricing for these procedures has created a positive level of increased reimbursement for the newer technologies, including both the PrepStain and the FocalPoint. 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 payors. 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 payors 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. The Medicare NLA for the various procedures that represent the technologies for cervical cancer screening demonstrates the general revenue potential. As a result of the Medicare Modernization Act of 2003, the clinical laboratory fee schedule will not change for five years and the reimbursement rates for 2006 will remain the same as for the previous two years. Below are the current NLA's (as of January 2006) for the various CPT codes

affecting our clinical laboratory business and an averaged reimbursement rate for the physician procedures based on relative value and conversion factor for those tests:

CPT Code	Description	NLA
88164	Cytopathology smears, cervical or vaginal (Bethesda System reporting); manual screening under physician supervision	$ 14.76
88147	Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision	$ 15.90
88148	Cytopathology smears, cervical or vaginal; screening by automated system with manual re-screening under physician supervision	$ 21.23
88142	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; manual screening under physician supervision	$ 28.31
88174	Cytopathology, cervical or vaginal (any reporting system), collected in a preservative fluid, automated thin layer preparation; with screening by automated system, under physician supervision	$ 29.85
88175	Cytopathology, cervical or vaginal (any reporting system), collected in a preservative fluid, automated thin layer preparation; with screening by automated system and manual re-screening, under physician supervision	$ 37.01
88112	Cytopathology, selective cellular enhancement technique with interpretation (e.g., liquid-based slide preparation) except cervical or vaginal	$120.00
88342	Immunohistochemistry / Immunocytochemistry (including tissue immunoperoxidase), each antibody. For morphometric analysis of IHC or ICC	$ 90.00

We have focused on obtaining coverage and reimbursement from major national and regional managed care organizations and insurance carriers throughout the U.S. We have 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 payor 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 payors 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 manually screened PrepStain thin-layer slide preparation procedure has achieved near universal coverage from third-party payors, as has the FocalPoint primary screening procedure for conventionally-prepared slides. The combined procedure of screening PrepStain slides on the FocalPoint has also achieved near universal coverage from the commercial and managed care insurers. Over the past year, laboratories utilizing the combined PrepStain/FocalPoint application have and continue to realize positive coverage and reimbursement from the vast majority of the third party payors. Throughout 2006 we expect to continue to realize the positive reimbursement for our technologies that we have received from the payor community and will work to continue to demonstrate diagnostic and economic value as new performance data is realized and made available. However, there can be no assurance that such favorable reimbursement will continue.

Molecular Diagnostic Products and Imaging Systems

As with our cervical cytology products, we expect that our molecular diagnostic reagents and imaging systems will be primarily purchased by medical institutions and laboratories that bill third-party payors such as government healthcare administration authorities, private health coverage insurers, managed care organizations and other similar organizations. Our ability to earn sufficient returns on these products will depend in part on the extent to which reimbursement for these products and related treatments will be available to our customers from third-party payors. Generic billing codes and reimbursement schedules exist for slide based immunohistochemistry and immunocytochemistry tests, including laboratory developed home brew assays, and these codes reflect incremental reimbursement for image analysis. All of our slide based molecular diagnostic reagents are being developed in

either immunohistochemistry or immunocytochemistry formats. For our *cervical screening assay*, it is likely that we will apply for either a new code or a code based on the Medicare NLA, to reflect the increased utility of the test. For blood based screening reagents, we will most likely be required to work with government healthcare administrative authorities to establish new billing codes and reimbursement schedules. While opportunities exist to enhance third party reimbursement if the results of future clinical trial and peer reviewed published studies support unique and high value clinical claims, third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of products to contain costs, and if they are successful, our ability to generate revenue growth and profitably from our molecular diagnostic products will be adversely affected.

Proprietary Technology and Intellectual Property

We currently hold over 110 issued or allowed United States patents. We have aggressively filed patents to protect the intellectual property generated by TriPath Imaging through work done in our TriPath Oncology segment for the molecular and imaging programs. We also hold approximately 40 foreign patents and have applied for patent protection for certain aspects of our technology in various foreign countries. Many of our patents were acquired in the merger of AutoCyte Inc. and NeoPath Inc. and the acquisition of the intellectual property and technology of Neuromedical Systems, Inc. We further expanded, and are expanding, our patent portfolio through the acquisition of the intellectual property of Cell Analysis Systems from BD in September 1999 and through our current work undertaken at TriPath Oncology. 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 2020. 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 using new discoveries in genomics and proteomics research to develop and commercialize molecular diagnostic products to improve the early detection and clinical management of certain types of cancer. We have active programs in development seeking to create tests to identify individuals with certain types of 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 will be based upon genomic and proteomic markers that were identified through discovery research conducted at Millennium under its research and development agreement with BD as well as other markers that have been or may be identified independently of that agreement. We have sublicensed certain of BD's rights to the proprietary markers. Our approach to marker discovery, identification, and prioritization is based on correlation with patient outcome and includes the evaluation of markers that have been previously identified by others as well as novel markers that have not been previously associated with our specific product indications. As a result, to ensure our freedom to utilize known markers and integrate them into our product candidates, we will in certain instances be required to license them from third parties. We are concurrently pursuing intellectual property protection for the novel markers that we have identified and the proprietary formulations that we are creating from the combination of either novel or known markers as well as for molecular imaging systems. However, we cannot be sure that we will be able to license markers on acceptable terms, if at all, or establish intellectual property protection of our novel markers, proprietary formulations or molecular imaging systems. During 2004 and 2005, we filed provisional patents that covered our discoveries, validation, and clinical assay format development in our cervical screening, breast prognosis and ovarian molecular oncology programs. 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 or that all of our issued patents are valid.

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 have registered trademarks in the United States for SurePath®, PrepStain®, FocalPoint®, AutoCyte®, AutoCyte Quic®, CytoRich®, ImageTiter®, PrepMate®, SlideWizard®, and TriPath Imaging®. We have pending U.S. trademark applications for ProEx™, SureDetect™, and TriPath Oncology™. Foreign registrations are maintained for several of our trademarks in Argentina, Australia, Brazil, Canada, Chile, China, the European Union, Hong Kong, Indonesia, Israel, Japan, Malaysia, Norway, the Russian Federation, South Africa, Switzerland, Taiwan and the United Kingdom. We have pending foreign trademark applications for ProEx™ and SureDetect™. In addition to trademark activity, we include 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. All other products and company names are trademarks of their respective holders.

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 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 and scale, 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, such as HPV vaccines, 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 the United States and abroad in thin-layer slide preparation is Cytyc Corporation (Cytyc). 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 also approved by the FDA as a replacement for the conventional Pap smear. They are also used for non-gynecological applications. Additionally, in Europe and in Latin America, there are a few growing number of thin-layer competitors offering manual method liquid based products. Currently these manufacturers have very little market share and, to our knowledge, are not actively pursuing FDA approval for their products. Nonetheless, they are creating competitive activity in many countries around the world. MonoGen, Inc., a privately-held company, submitted a PMA application for the MonoPrep Pap Test to the FDA during the fourth quarter of 2004. On December 20, 2005 Oxbow Equities Corp. announced that its 46% owned investee company, MonoGen, Inc., received an approvable letter from the FDA related to its MonoPrep® Pap Test. The Pap test relies on a filtration separation system for processing Pap samples. The letter specified that the MonoGen pre-market approval application (PMA) is approvable subject to certain conditions being met, including a satisfactory outcome from the inspection of the company's manufacturing facilities and final agreement on labeling.

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 thin-layer and conventional Pap smear

slides. In June 2003, however, Cytyc announced that it had received approval from the FDA for commercialization of its ThinPrep Imaging System, an interactive computer system that is designed to assist cytotechnologists in the primary screening and diagnosis of its thin-layer slides. We are currently engaged in litigation with Cytyc, as to whether its ThinPrep Imaging System infringes certain of our patents. See Item 3 — "Legal Proceedings" below. Other competitors include Clarient, Inc. (formerly ChromaVision Medical Systems, Inc.) and 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 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.

Molecular Diagnostic Reagents

Competition in the field of cancer diagnostic products continues to be 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 IHC and *in situ* hybridization (ISH) techniques on tissue specimens. The primary companies currently competing in this area are Dako Corporation and Ventana Medical Systems, Inc. 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., dia Dexus, Genomic Health, Molecular Profiling Institute, Veridex, Ciphergen, 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 that we are unable to obtain or more rapidly than we can.

Government Regulation

The design, testing, manufacture, labeling, distribution, advertising, promotion 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 Federal Food, Drug, and Cosmetic Act, or the 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. FDA may impose conditions of approval or restrictions on the sale, distribution, or use of devices. Pursuant to the FDC Act, the FDA regulates the pre-clinical and clinical testing, design, manufacture, storage, labeling, distribution, record keeping, reporting, sales, marketing, advertising and promotion of medical devices in the United States. The FDA also regulates the import and export of medical devices. Noncompliance with applicable requirements, including good clinical practice requirements and QSR requirements, can result in enforcement action which can include any of the following sanctions: the suspension or withdrawal of authorization of clinical studies, the refusal of the government to grant pre-market approval or premarket clearance for devices, suspension or withdrawal of clearances or approvals, warning letters, operating restrictions, total or partial suspension of production, distribution, sales and marketing, customer notification, orders for repair, replacement, or refund, 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., establishment registration, labeling, recordkeeping, reporting, and adherence to FDA-mandated quality system requirements, including QSR), and, in some cases, pre-market notification under Section 510(k) of the FDC Act. Class II devices are subject to general controls, in most cases to pre-market notification under Section 510(k) of the FDC Act, 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, including life-sustaining, life-supporting and implantable devices, and also "new" devices that were not on the market before May 28, 1976 and for which the FDA has not made a finding of "substantial equivalence" based on a pre-market notification. Class III devices usually require data from clinical testing that demonstrates the device is safe and effective, and must have FDA approval of a premarket approval application, or PMA, under Section 515 of the FDC Act, prior to marketing and distribution. The conduct of clinical studies is subject to FDA regulations, including requirements for institutional review board (or IRB) approval, informed consent, record keeping, and reporting. Clinical studies of "significant risk" devices, including many Class III devices, also require FDA approval of an investigational device exemption (IDE) application prior to initiating clinical trials. Clinical trials are conducted with the oversight of the IRB at each study site. Our PrepStain and FocalPoint products, when intended for gynecological use, are regulated as Class III medical devices. In the future, some of our molecular diagnostic products may be regulated as Class III devices. In addition, to the extent molecular diagnostic products may be intended for use as prognostic tests for selecting subsets of patients most likely to benefit from drug therapies, such products may be studied in clinical trials of drug products under the FDC Act regulatory provisions governing pharmaceutical clinical trials.

FDA has developed special rules for *in vitro* reagents that are not approved or cleared as diagnostic products. FDA has imposed restrictions on the manufacture, labeling, sale, distribution, advertising, promotion and use of Analyte Specific Reagents (ASRs). FDA defines ASRs as antibodies, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. In simple terms, an ASR is the active ingredient of an in-house laboratory test and is used, in conjunction with general purpose reagents and general purpose instruments, by a laboratory that must be certified as high complexity under the Clinical Laboratory Improvement Act of 1998 as amended (CLIA) and has developed and performs an in-house ("home brew") test or laboratory testing service. The in-house assay is used to test patient specimens only by the clinical laboratory that developed and validated the test for its own in-house use. It is the responsibility of the laboratory using the ASR to develop the test procedures and to take responsibility for establishing and maintaining performance. Most ASRs are exempt from premarket notification under Section 510(k) of the FDC Act, but they are subject to GMP requirements and the restrictions on sale, distribution and use imposed by FDA regulation. ASRs intended for use in blood banking tests are not exempt from

premarket notification. In addition, some ASRs are subject to premarket approval (PMA) requirements, including ASRs used in diagnosing a contagious condition that could be fatal (such as HIV) or in blood donor screening. In addition, FDA regulates Research Use Only (RUO) products, which by their required labeling are not intended for use in diagnostic procedures. The clinical application of these RUO products is unknown and commercialization is limited to research purposes only. Products and reagents 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. For devices with an approved PMA, the manufacturer must submit periodic reports containing information on safety and effectiveness and other information specified in FDA regulations. 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 ASRs, are and will be subject to pervasive and continuing regulation by the FDA, including record-keeping and reporting requirements. We have established and maintain a system for tracking FocalPoint and PrepStain systems through the chain of distribution. 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. We are also required to report to the FDA about corrections to our device products and about any market removals.

Product labeling and promotional activities are also subject to scrutiny by the FDA. Product advertising and promotional activities are also subject to regulation by the Federal Trade Commission. We, and our distributors, may only promote products for their approved indications. In this regard, violations of promotional requirements may, in addition to implicating violations of the FDC Act, also involve violations of the False Claims Act, the Medicare and Medicaid "anti-kickback" laws, and other federal or state laws that the government may utilize to enforce these and related requirements. In addition to the government bringing claims under the Federal False Claims Act, *qui tam*, or "whistleblower," actions may be brought by private individuals on behalf of the government. Also, competitors may bring litigation under the Lanham Act relating to product advertising. 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.

We are subject to both routine and directed inspections by the FDA for compliance with regulations with respect to design control activities, manufacturing, testing, distribution, storage, product labeling, recordkeeping, reporting, sales, advertising and promotional activities. We have been periodically inspected by the FDA at both our Burlington, North Carolina and Redmond, Washington facilities. In August 2005, we underwent a routine quality system inspection at our Redmond facility. This was concluded with no deficiencies noted. In April 2005, a good clinical practices inspection occurred at our Redmond facility related to FocalPoint LGS submission. A Form 483 was issued and observations were corrected satisfactorily. In 2004, we underwent a routine inspection at our Burlington facility to conclude the move of PrepMate manufacturing from Redmond to Burlington in addition to GMP compliance.

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;

- impose administrative civil penalties; and
- initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil or criminal penalties against us, our officers or employees.

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

In the future, the Company may seek FDA approval of medical products other than medical diagnostic devices. The regulatory requirements for these products are similar in scope to the requirements described above for medical devices, particularly with respect to the need for, and the degree of FDA oversight of, pre-clinical and clinical testing, pre-market approval, manufacturing, labeling, recordkeeping, promotion, sale and post-market reporting.

Clinical Laboratory Improvement Act of 1988 (CLIA) and State Laboratory Laws

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 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.

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/or 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. We have 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 EU. *In vitro* medical devices, including our PrepStain system, FocalPoint Imaging System, molecular diagnostic reagents, and molecular imaging systems, must now comply with the EC's In-Vitro Diagnostic Medical Devices Directive also known as IVDD. The IVDD was published in the Official Journal of European Communities in December 1998. The EU member states were required to implement the IVDD into national law by December 1999 on the implementation date of the IVDD. A transition period, which ended December 6, 2003, applies to all devices placed on the market in the EU. By the end of this transition period, our products were required to comply with the requirements of the IVDD and member-state local language requirements. At such time, products not bearing the CE mark would have been prohibited from being commercially distributed in EU member countries. Products bearing the CE mark may circulate freely within the EEA, but member states may restrict or prohibit the marketing of CE-marked devices pursuant to the safeguard clause of the IVDD if the member state determines a particular device may compromise the health and/or safety of patients or users. In December 2003, we declared that we satisfied the essential requirements of the IVDD, which allows us to add the CE mark to our products including antibody-based diagnostic tests with the appropriate registration.

Other European countries may enact national laws that would conform to the IVDD. EU and EEA member states are required to implement national laws that are consistent with IVDD. However, some European countries have established national regulations relating to *in vitro* diagnostic medical devices, including rules governing their supply, advertising, promotion, pricing or reimbursement. The IVDD and implementing 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.

In addition, Canadian regulations have similar, but distinct, requirements as those noted for the EU's IVDD, which also became effective January 1, 2003. We undertook and achieved compliance with those requirements.

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, 2005, we employed approximately 340 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.	57	President, Chief Executive Officer and Chairman of the Board
Stephen P. Hall	55	Senior Vice-President, Chief Financial Officer
Ray W. Swanson	50	Senior Vice-President, Commercial Operations
Johnny D. Powers, Ph.D.	44	Senior 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., a supplier of cytology screening and anatomic pathology diagnostic equipment and services to laboratories, 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-Behring's platelet function business. As President of Dade-Behring'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. is our Senior Vice-President and General Manager of TriPath Oncology. He previously 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, Inc., 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 earned 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 approximately 70,000 square feet of space devoted primarily to our Commercial Operations manufacturing, warehousing, administrative, research and development, engineering functions, educational and corporate office space at 780 Plantation Drive, Burlington, North Carolina under a lease expiring in December 2018. In 2003, we renegotiated our Redmond, Washington lease in order to reduce office and manufacturing space leased. At the end of 2004 an additional lease obligation for 30,000 square feet expired and was not renewed. We now lease approximately 20,000 square feet of office and manufacturing space in Redmond, Washington under an operating lease. That operating lease expires in December 2007. We also lease approximately 4,000 square feet of office space in Brussels, Belgium, under an operating lease expiring in January 2013. We also lease approximately 1,650 square feet of office space in Grenoble, France under an operating lease expiring in December 2014. We lease approximately 22,000 square feet near Research Triangle Park, in Durham, North Carolina devoted primarily to the activities of TriPath Oncology. This lease has a seven-year term expiring in June 2009. We believe that our facilities and other available office space will be adequate for our current and future planned needs.

Item 3. ***Legal Proceedings***

We compete with Cytyc Corporation (Cytyc) with respect to the sale of our FocalPoint and Cytyc's sale of its ThinPrep Imaging System. We believe Cytyc's ThinPrep Imaging System infringes our patents. In 2003 we filed a lawsuit seeking damages and injunctive relief to stop such infringement and Cytyc filed a separate action seeking a declaratory judgment in their favor. On January 5, 2004, those suits were consolidated into a single action in the United States District Court for the District of Massachusetts. The case numbers for the consolidated action are 1:03-CV-12630-DPW and 1:03-CV-11142-DPW. The case numbers are for reference only and the corresponding pleadings are expressly not incorporated into this document by reference. Fact and expert discovery have been completed. A claim construction or Markman ruling was issued by the court on November 28, 2005. The court has entered a scheduling order setting forth certain deadlines through June 2006, including those for conducting mediation and filing of summary judgment motions. We anticipate that a trial will be scheduled sometime in late 2006 or the first half of 2007. We are unable to predict the ultimate outcome. Similarly, we are unable to predict the potential effect on our business and results of operations that any outcome may ultimately have.

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

There were no matters submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2005.

PART II

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

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 31, 2004:		
First Quarter	$10.95	$7.70
Second Quarter	$10.45	$8.36
Third Quarter	$ 9.49	$7.00
Fourth Quarter	$ 9.52	$6.19
Year ended December 31, 2005:		
First Quarter	$ 9.20	$6.85
Second Quarter	$ 8.97	$6.15
Third Quarter	$ 9.45	$6.54
Fourth Quarter	$ 7.84	$5.55

On February 27, 2006, the last reported sales price of the Common Stock on the Nasdaq National Market was $6.78 per share. As of February 27, 2006, there were 38,382,639 shares of our Common Stock outstanding, which were held by 339 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 Item 7. — "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.

	2001	2002	2003	2004	2005
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	$ 27,017	$ 37,485	$53,764	$68,504	$85,961
Gross profit	13,921	22,563	35,387	47,274	59,926
Research and development(1)	7,828	10,259	14,295	15,162	15,755
Selling, general and administrative	28,777	30,786	30,011	31,778	37,992
Operating income/(loss)	(22,684)	(18,482)	(8,919)	334	6,179
Net income/(loss)	(21,680)	(18,064)	(8,538)	605	6,500
Earnings/(loss) per share(2)					
Basic	$ (0.61)	$ (0.48)	$ (0.23)	$ 0.02	$ 0.17
Diluted	$ (0.61)	$ (0.48)	$ (0.23)	$ 0.02	$ 0.17
Weighted-average shares outstanding					
Basic	35,467	37,438	37,626	38,006	38,218
Diluted	35,467	37,438	37,626	39,151	39,270

	December 31,				
	2001	2002	2003	2004	2005
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents, and short-term investments	$55,976	$32,571	$20,954	$18,949	$22,457
Working capital	62,898	38,837	33,446	35,909	42,261
Total assets	96,748	73,951	65,928	67,534	76,968
Long-term obligations	5,001	220	8	—	98
Total stockholders' equity	77,291	59,177	52,371	58,546	65,959

(1) Includes regulatory expenses.

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

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations (amounts in thousands, except share and per share amounts)*

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.

Overview

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 expertise 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 our efforts to develop new molecular diagnostic products for malignant melanoma and cancers of the cervix, breast, ovary, and prostate.

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 current products; and (2) TriPath Oncology, our wholly-owned subsidiary, through which we manage the development and market introduction of molecular diagnostic products for cancer.

Our Commercial Operations unit is a commercial engine organized to grow sales, drive margin and generate cash. TriPath Oncology is the development engine of a broad based gene discovery program created to develop new molecular products for the early detection and clinical management of cancer. Today, our revenues are primarily generated through our Commercial Operations unit from the sale of our cervical cytology screening products, and in particular, the SurePath liquid-based Pap test. In 2005, for the first time in our history, we generated significant revenues from the sale of some of the molecular products that we are developing in TriPath Oncology. In 2006, we expect to continue to generate revenues from the early commercialization of TriPath Oncology's molecular diagnostic products and molecular imaging systems and we believe that sales related to these developing products will significantly impact our growth in the future.

2005 was our second consecutive profitable year, with earnings per share of $0.17, reflecting a $5,895 improvement in net income from 2004. We grew our revenues by nearly 26%, primarily as a result of a 30% increase in revenues generated from the worldwide sales of SurePath reagents and disposables. Gross profit grew nearly 27% as we experienced a gross margin on incremental revenues in excess of 72%. Our commercial operations segment generated operating income of $22,075, a $7,331 increase from 2004. We were profitable and cash flow positive in all four quarters during the year. Our TriPath Oncology segment generated revenues of $1,804. By year-end, cash and cash equivalents had increased by $3,508 from year-end 2004.

We achieved a number of key milestones in 2005 that drove our yearly financial results and represent important growth opportunities for the future:

- Our agreements with Quest Diagnostics and LabOne, recently acquired by Quest Diagnostics, contributed significantly to increased penetration of the large commercial laboratory segment in the U.S., a market segment to which we had only limited access prior to 2005.
- Our expanded U.S. sales force enabled us to leverage the opportunity for growth that has been created by our growing relationships with the large commercial laboratories as the number of SurePath liquid based Pap tests sold in the U.S. grew 41% from the prior year.
- We continued to gain momentum outside the U.S. as SurePath liquid based Pap tests sold outside the U.S. grew 26% from 2004.
- We received FDA approval for expanded claims for our SurePath liquid-based Pap test to include processing of pre-coated slides with the PrepStain Slide Processor.
- We received several clearances from the FDA, including a 510(k) clearance for processing of the Ventana estrogen and progesterone receptor tests on our interactive histology imager and a 510(k) clearance from the FDA for the VIAS when used with tissues stained for HER-2/neu.
- The results of external research studies of both our cervical and breast staging biomarkers confirmed previously reported results from in-house studies.
- We introduced ASRs and reagent enabling products into the marketplace.
- We transitioned our microscopic slide based assays for cervical screening and breast cancer staging into clinical trials;
- We completed development of our ELISA formatted blood based RUO reagents for ovarian screening.
- We saw the early commercialization of our VIAS resulting from a worldwide agreement with Ventana to sell and distribute a Ventana branded version of our interactive histology imager.

Challenges

Our primary challenges in 2006 relate to leveraging the pathways for growth that we have created over the past five years.

We have made significant progress in penetrating the cervical cytology marketplace with our SurePath liquid-based Pap test since its regulatory approval in 1999. We continue to believe that there is additional ground to be gained despite the fact that we continue to face significant competitive pressure. Our growing relationship with the large commercial laboratory segment presents a significant continuing growth opportunity in 2006. Our success in 2006 will in large part depend on our ability to continue conversion of current and other large commercial laboratory customers. We continue to face the challenge of expanding our cervical cytology business in a heavily contested market segment while maintaining and growing our business within our traditional customer base. We will need to succeed at both if we are to achieve the revenues we have forecasted for 2006 (see Outlook below).

During 2005, we completed the expansion of our domestic sales force that we initiated in the third quarter of 2004. We face the challenge of ensuring the earliest possible return on this increased investment in sales and marketing by accelerating our growth in revenues generated from increased sales to our large commercial laboratories as well as to our traditional customer base. The expanded sales organization also presents new challenges for our sales management, given our increased size and expanded geographic coverage.

Given the accelerated traction we gained outside the U.S. in 2004 and 2005, we expect that our sales outside the U.S. will contribute significantly to our growth in 2006 and beyond. The primary challenges we face outside the U.S. include governmental decisions regarding licensing and reimbursement, competition and regional variations in practices and product acceptance. In addition, since we sell predominantly through regional distributors in all markets outside the U.S. except for Canada, we face the challenges associated with managing these independent sales distributors in most international markets and our success, to a large extent, is dictated by the performance of

the regional distributors. In Canada, where we sell through our own sales force, our greatest challenge in 2006 relates to our ability to translate the success we have enjoyed to date in the province of Ontario to other population centers as well as managing contract renewals which begin in 2006.

Successful movement of some of our cytology product offerings through the FDA approval process is a continuing challenge that we will face in 2006. In September 2005, we withdrew the PMAS we had submitted to the FDA for the FocalPoint GS Imaging System, having been notified by the FDA that the PMAS must be amended to include additional data. We expect to initiate collection of new data in support of a FocalPoint GS PMAS application early in the first quarter of 2006, complete the collection of new data in the first half of 2006 and resubmit our PMAS shortly thereafter. In the first quarter of 2005 we announced that we had withdrawn our pre-market approval supplement (PMAS) submission to the FDA to seek approval for expanded claims for the SurePath liquid-based Pap test to include an out-of-vial option for testing cervical cells collected using the SurePath Test Pack for the presence of high risk HPV DNA with the Digene hc2 High-Risk HPV DNA Test™. We resubmitted this PMAS, using new and existing data and data analyses, in the fourth quarter of 2005. There can be no assurance that we will obtain FDA approval for our HPV-related application or for FocalPoint GS when expected, if at all, and the failure to achieve such approvals may materially impact our revenues.

In 2006, we also face the challenges and risks associated with the execution of new clinical trials in support of our intended FDA submissions relating to our developing molecular diagnostic products, including new 510(k) notifications to process additional Ventana assays on our interactive histology imaging system and Pre-Market Approval applications for our molecular products for breast cancer staging and cervical cancer screening. The length, size, complexity, cost, and potential outcome of these clinical trials will be driven by our ability to craft and execute a reasonable and well-designed clinical trial protocol. Successful execution of these clinical trials will ultimately impact revenues that we expect to generate from the sale of these products in the future. There can be no assurance that we will obtain FDA clearance for additional applications for VIAS or approval for our molecular products for breast cancer staging and cervical cancer screening.

We face challenges and risks in 2006 that primarily reflect the progress we have made in our molecular diagnostics development programs to date and the fact that some of these programs will now move into the next stages of development. Our approach to marker discovery, identification and prioritization is based on correlation with patient outcome and includes the evaluation of markers that have been previously identified by others as well as novel markers that have not been previously associated with our specific product indications. As a result, to ensure our freedom to utilize known markers and integrate them into our product candidates, we will in certain instances be required to license them from third parties. We are, concurrently, pursuing intellectual property protection for the novel markers that we have identified as well as the proprietary formulations that we are creating from the combination of either novel or known markers. There can be no assurance that we will be able to license markers on acceptable terms, if at all, or establish intellectual property protection for our novel markers and proprietary formulations or molecular imaging systems.

We expect that domestic and international sales of some of our molecular reagents and molecular imaging systems will increasingly contribute to our revenues for 2006 (see Outlook below). As a result, we will face the challenge of introducing these as either RUO products, ASRs or Class I IHCs in the U.S. as well as the challenges associated with the international introduction of products not yet approved for use in the U.S. The success of our slide based cervical staging, cervical screening, breast staging products, our blood-based ovarian screening product, and our molecular imaging systems will depend, to a large extent, on the outcome of our ongoing in-house studies, as well as, external research studies that are being generated by independent investigators and clinical trials. As we collect data from both internal and external research studies we face the challenge of building the clinical case for the value of these developing products and, the challenge of positioning ourselves for clinical trials; and for those product candidates in clinical trials, we face the challenge of translating the results of these studies into market opportunity, the challenges of securing regulatory approval, and the challenge related to preparing the market for a broader introduction of these products in 2006 and beyond. We also face the challenges associated with the late stage development of our ovarian screening assay, selection of a multiplexing testing platform for our blood based screening assays which would allow for simultaneous testing for multiple markers on a small volume of blood, adaptation of our ELISA formatted RUO ovarian screening reagents to chosen multiplexing testing platform and for continuing clinical studies related to our melanoma staging product.

Our sales and distribution agreement with Ventana is of both short and long term significance. In the short term, it is an opportunity to penetrate the Anatomic Pathology marketplace with our interactive imager and, as a result, to generate new revenue streams as the agreement provides for potential capital equipment and fee per use revenues which began in 2005. In the long term, it is an opportunity to achieve placement of our molecular imaging system in advance of the commercial introduction of our slide-based breast staging product along with a battery of complementary assays from Ventana. The challenges that we will face as a result of this venture include obtaining additional FDA clearances for Ventana assays to be processed on the product and, if necessary, additional FDA or other regulatory clearances or approvals with respect to the assays and imager, and the challenges associated with supporting Ventana in its market introduction of the product.

As always, we face the ongoing challenges associated with balancing our existing cash reserves against the costs associated with effective research, development, marketing and selling programs.

Results of Operations

Non-GAAP Financial Measures

In May 2004, we entered into a multi-year agreement with Quest Diagnostics Incorporated ("Quest Diagnostics") pursuant to the terms of which Quest Diagnostics uses our SurePath and PrepStain products. In connection with the agreement, we issued Quest Diagnostics warrants with respect to an aggregate of 4,000,000 shares of our common stock, which are described in the following table:

Warrant	Shares Subject to Warrants	Exercise Price (per share)	Warrant Expiration Date	Vesting Status
First Tranche	800,000	$ 9.25	May 2007	Currently Exercisable
Second Tranche	200,000	$10.18	May 2007	Currently Exercisable
Third Tranche	500,000	$10.64	May 2007	Currently Exercisable
Fourth Tranche	1,000,000	$11.56	May 2008	Exercisable Upon Achievement of Sales Milestone
Fifth Tranche	1,500,000	$12.03	May 2008	Exercisable Upon Achievement of Sales Milestone

The warrants permit exercise on a net issuance basis and are subject to a lock-up provision, which prohibits sales and other transfers of the underlying shares for a two-year period ending in May 2006, at which point 50% of the shares underlying warrants then exercisable may be transferred, and subjects the remaining underlying shares to an additional one year lock-up.

— First Tranche Warrants

The First Tranche warrants were exercisable upon the commencement of the agreement with Quest Diagnostics. Using the guidance in the FASB's Emerging Issues Task Force Release 01-9, *"Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products),"* these warrants were valued (on the basis of the fair value of the warrants at the date of grant) using a Black-Scholes pricing model upon issuance at $3,896, which represented a deferred sales discount. The value of the warrants was recorded as additional paid-in capital and the resulting deferred sales discount is being amortized on a straight-line basis against revenues over the five-year term of the agreement.

— Sales-Based Milestone Warrants

Our agreement with Quest Diagnostics links the exercisability of the Second Tranche, Third Tranche, Fourth Tranche and Fifth Tranche warrants to the achievement of sales-based milestones, which have been met for the Second Tranche and Third Tranche. These milestones are based on the volume of SurePath tests purchased by Quest Diagnostics within specified time periods. When it becomes probable that a tranche of warrants will become exercisable upon the achievement of the applicable sales-based milestone, we accrue the resulting sales discounts over the related number of tests in the six-month period for which the milestone is achieved as further described below.

— Second and Third Tranche Warrants

During 2005, the Second and Third Tranche warrants vested upon the achievement of the sales-based milestone applicable to those warrants. Using the guidance in the FASB's Emerging Issues Task Force Release 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"* ("EITF 96-18"), the 200,000 Second Tranche warrants were valued at $224 using a Black-Scholes pricing model, which was recorded as a reduction of revenues with a corresponding credit to additional paid-in capital. Additionally, the 500,000 Third Tranche warrants were valued at $275 using a Black-Scholes pricing model, which was recorded as a reduction of revenues with a corresponding credit to additional paid-in capital.

When and if it becomes apparent that any of the remaining tranches of currently unexercisable warrants held by Quest may vest upon the achievement of the applicable sales-based milestone, we will accrue the resulting deferred sales discounts over the related number of tests in the six-month period for which the warrants were earned. Since the deferred sales discount relating to these tranches of warrants will be amortized over only six months, if and when such warrants vest, the quarterly impact upon the future quarters in which they are recorded will be disproportionately large compared to the ongoing quarterly non-cash sales discount of $195 recorded in connection with the First Tranche warrants.

— Summary

During 2005 and 2004, we recorded $1,278 and $519, respectively, of amortization of deferred and accrued sales discounts as a reduction of revenues.

The following tables present pro forma versions of our revenues, gross profit, net income and earnings per share (basic and diluted) to illustrate our results from operations excluding the recorded non-cash sales discount relating to the warrants held by Quest. The table presents the most comparable GAAP measure to each non-GAAP measure, as well as the reconciliation to the corresponding GAAP measure. Our management believes that these non-GAAP financial measures provide a useful measure of our results of operations, excluding discounts that are not necessarily reflective of, or directly attributable to, our operations. We believe that these non-GAAP measures will allow investors to monitor our ongoing operating results and trends, gain a better understanding of our period-to-period performance, and gain a better understanding of our business and prospects for future performance. These non-GAAP results are not in accordance with, or an alternative for, generally accepted accounting principles and may be different from similar non-GAAP measures used by other companies.

	Year Ended December 31, 2005		
	GAAP	Reconciliation: Add Back Non-Cash Sales Discount	Non-GAAP
	(In thousands, except per share data)		
Revenues	$85,961	$1,278	$87,239
Gross profit	59,926	1,278	61,204
Net income	6,500	1,278	7,778
Earnings per share:			
Basic	$ 0.17	$1,278 to revenues used in calculation	$ 0.20
Diluted	$ 0.17	$1,278 to revenues used in calculation	$ 0.20

	Year Ended December 31, 2004		
	GAAP	Reconciliation: Add Back Non-Cash Sales Discount	Non-GAAP
	(In thousands, except per share data)		
Revenues	$68,504	$519	$69,023
Gross profit	47,274	519	47,793
Net income	605	519	1,124
Earnings per share:			
Basic	$ 0.02	$519 to revenues used in calculation	$ 0.03
Diluted	$ 0.02	$519 to revenues used in calculation	$ 0.03

Years ended December 31, 2005 and 2004

The tables below summarize our segment results for the years ended December 31, 2005 and 2004. All intersegment revenues have been eliminated. Comments made throughout this discussion related to our segments refer to the figures in these tables:

	Commercial Operations			
	2005	2004	Change vs 2004	% Change
		(In thousands)		
Revenues	$84,157	$67,862	$16,295	24.0%
Cost of revenues	24,981	21,072	3,909	18.6%
Gross profit	59,176	46,790	12,386	26.5%
Operating expenses:				
Research and development	2,004	2,005	(1)	0.0%
Regulatory	2,450	3,263	(813)	(24.9)%
Sales and marketing	23,926	18,126	5,800	32.0%
General and administrative	8,721	8,652	69	0.8%
	37,101	32,046	5,055	15.8%
Operating income	$22,075	$14,744	$ 7,331	49.7%

	TriPath Oncology			
	2005	2004	Change vs 2004	% Change
		(In thousands)		
Revenues	$ 1,804	$ 642	$ 1,162	181.0%
Cost of revenues	1,054	158	896	567.1%
Gross profit	750	484	266	55.0%
Operating expenses:				
Research and development	10,348	9,275	1,073	11.6%
Regulatory	953	619	334	54.0%
Sales and marketing	514	514	—	0.0%
General and administrative	4,831	4,486	345	7.7%
	16,646	14,894	1,752	11.8%
Operating loss	$(15,896)	$(14,410)	$(1,486)	10.3%

Revenues

Total Revenues. Total revenues for the year ended December 31, 2005 were $85.961, a 25.5% increase from revenues of $68,504 for 2004. Compared with 2004, this net increase in total revenues was primarily due to (i) an increase in reagent sales of $15,585, or 29.6%, (ii) an increase in instrument sales of $927, or 13.0%, and (iii) an increase of $945, or 10.9%, in other revenues, which consisted primarily of fee-per-use sales, service on system placements, various core product accessories and freight.

Commercial Operations Revenues. Revenues for the year ended December 31, 2005 from the Commercial Operations segment were $84,157, a 24.0% increase from revenues of $67,862 for 2004. In 2005, reagent sales increased $15,555, or 29.5%, worldwide compared with 2004. Domestic sales of our SurePath and PrepStain reagents increased $12,660, or 31.2%, while international sales increased $2,895, or 23.8%. As a percentage of total revenues, reagent and disposable sales increased to 81.1% in 2005 from 77.6% in 2004. Worldwide, we acquired in excess of 75 new SurePath laboratory customers, 31 in the U.S. Domestically, net realized revenue per test in 2005 decreased 11.3% from 2004. This resulted from a decline in average price per test that was predominantly attributable to a continuing shift in our revenue mix as a significantly larger percentage of revenues resulted from sales in the U.S. to the large commercial laboratory segment. The large commercial laboratory segment accounted for 41.0% of all SurePath cervical cytology test kits sold in the U.S. in 2005 as compared to 24.1% in 2004. The increase in business from large commercial laboratory customers is a result of our continued growing relationships with Quest Diagnostics, LabCorp and AmeriPath and of our continued focus of our sales and marketing efforts on the large commercial laboratory segment. The number of tests sold to our traditional and more fully penetrated customer base grew 17.9% in 2005 versus 2004. Our SurePath Test Pack share of the domestic Pap smear testing market in the U.S. was approximately 21.5% at the end of 2005 versus approximately 15% at the end of 2004.

Sales of instruments decreased $100, or 1.4%, during 2005 compared to 2004. Worldwide sales of PrepStain instruments for preparation of thin-layer slides for the SurePath liquid-based Pap test increased by $598, or 25.5%, during 2005, including an international increase of $1,015, or 57.4%. Revenues related to the sale of PrepStain instruments decreased $417, or 72.5%, domestically compared with 2004. We placed 58 PrepStain instruments in the U.S., 56 under reagent rental agreements, and 50 outside the U.S., 2 under reagent rental agreements, during 2005. This compares with 76 PrepStain units placed in the U.S., 66 under reagent rental agreements, and 46 units placed outside the U.S., 2 under reagent rental agreements, in 2004. Worldwide sales of FocalPoint systems decreased $549, or 9.4%, during 2005. In the U.S., revenues generated from the sale of FocalPoint systems increased $971, or 78.6%, while revenues generated from fee-per-use agreements decreased $58, or 2.7%, (revenues generated from fee-per-use agreements are considered Other Revenue). Revenues generated from the sale and rental of FocalPoint systems outside the U.S. decreased $1,520, or 47.2%, primarily due to decreased instrument sales in Europe. In 2005 we placed 13 units net of returns in the U.S., 6 under fee-per-use agreements net of returns, and sold 6 units, net of returns, outside the U.S. This compares with 11 units, net of returns, in the U.S., 5 under fee-per-use agreements, and 10 units sold outside the U.S., in 2004. Revenues recorded for SlideWizard system sales, all international, decreased $149, or 65.3%, between 2005 and 2004. We placed 6 SlideWizard units in 2005 compared with 13 in 2004.

Other revenues, consisting primarily of fee-per-use sales, service on system placements, various core product accessories and freight increased $840, or 10.3%, during 2005. FocalPoint fee-per-use revenues decreased $58, or 2.7%, in 2005 compared to 2004, while service revenues worldwide increased $512, or 21.2%, over 2004. Freight and royalty revenues also increased $433, or 36.2%, from 2004 to 2005. Other net decreases were $47.

TriPath Oncology Revenues. Revenues recorded at TriPath Oncology increased $1,162 from $642 in 2004 to $1,804 in 2005, an increase of 180.9%. This increase is largely attributable to $1,157 of sales of our Interactive Histology Imaging System, an increase of $1,027, or 790.0%. Additionally, sales of our cervical reagents and fee-per-use revenues increased $147 in 2005, with no such sales recorded in 2004.

Gross Margin

Total Gross Margin. Gross margin improved from 69.0% in 2004 to 69.7% in 2005. Our Commercial Operations segment is primarily responsible for the increase in gross margin because of continued growth in higher margin reagent and disposable sales and lean-based efficiencies in our manufacturing operations, which includes

tools such as Value Stream Mapping, One-Piece Flow, Kanban Materials Management and Kaizen implementation methodology.

Commercial Operations Gross Margin. Gross margin in our Commercial Operations segment improved from 68.9% in 2004 to 70.3% in 2005. Gross margin increased as the result of continued growth in higher margin reagent and disposable sales and lean-based efficiencies in our manufacturing operations, as mentioned above.

TriPath Oncology Gross Margin. Gross margin in our TriPath Oncology segment was 41.6% in 2005 compared with 75.4% in 2004. The decrease in gross margin is the result of increased sales of our lower-margin Interactive Histology Imaging System to Ventana, comprising the majority of 2005 segment revenues, versus high-margin fee revenues dominating TriPath Oncology's revenues in 2004.

Research and Development

Total 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 2005 were $12,352, a $1,072, or 9.5%, increase from $11,280 in 2004.

Commercial Operations Research and Development. Our Commercial Operations segment incurred research and development expenses of $2,004 in 2005 versus $2,005 in 2004. Research and development expenditures relating to our Commercial Operations segment reflect research activity related to our cervical cytology product line and the development of manufacturing capabilities for new molecular tests that we are developing. As manufacturing operations are managed through our Commercial Operations segment, costs related to the manufacture of our new molecular tests are assigned to our Commercial Operations segment.

TriPath Oncology Research and Development. Our TriPath Oncology segment incurred research and development expenses of $10,348 and $9,275 for 2005 and 2004, respectively, an increase of $1,073, or 11.6%. These expenditures reflect the continued development of our interactive histology imaging system and molecular diagnostic markers, reagents and assays.

Regulatory

Total 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, 2005 were $3,403, representing a $479, or 12.3%, decrease from $3,882 in 2004.

Commercial Operations Regulatory. Regulatory expenses were $2,450 in the Commercial Operations segment in 2005, compared with $3,263 in 2004, a decrease of $813, or 24.9%. This reduction in regulatory expense primarily reflected the winding down of clinical trials; in particular, the FocalPoint GS and HPV related clinical trials that were initiated in 2003.

TriPath Oncology Regulatory. There were $953 of regulatory expenses incurred by the TriPath Oncology segment in 2005 versus $619 in 2004, an increase of $334, or 54.0%. These additional expenses in 2005 related to increased activities associated with beginning the clinical trial activities for our cervical and breast staging products, which will commence in 2006.

Sales and Marketing

Total 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 2005 were $24,440. This represented a $5,800, or 31.1%, increase from $18,640 in 2004 which was attributable to our commercial operations segment.

Commercial Operations Sales and Marketing. Sales and marketing expenses for 2005 incurred by the Commercial Operations segment were $23,926. This represented a $5,800, or 32.0%, increase from $18,126 in 2004. This year-over-year increase predominantly reflects the effects of the sales force expansion we began in the third quarter of 2004 and the reintroduction of a number of targeted marketing programs introduced during 2005.

TriPath Oncology Sales and Marketing. The TriPath Oncology segment incurred sales and marketing expenses of $514 for each of 2005 and 2004. Sales and marketing activities at TriPath Oncology are targeted primarily towards the potential launch, and pre-launch, activities related to our molecular diagnostic products. For both 2004 and 2005 these costs were directed more toward market development activities than to sales related activities.

General and Administrative

Total 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 $13,552 in 2005 compared with $13,138 in 2004. This reflects a net increase of $414, or 3.2%, between 2004 and 2005. The most significant components of this net increase include increases related to: (1) costs related to professional fees, principally additional costs incurred to comply with the requirements of Section 404 and 302 of the Sarbanes-Oxley Act of 2002 and (2) lease expense related to upgrading some of our information technology infrastructure. Partially offsetting these increases were reductions of expense versus 2004 in the following areas: (1) legal fees, (2) depreciation expense as certain assets became fully depreciated during 2005, which is consistent with our move in recent years to utilize an operating lease line of credit to finance capital purchases, and (3) corporate insurance, primarily in our property and casualty and director and officer programs.

Commercial Operations General and Administrative. General and administrative expenses incurred by the Commercial Operations segment increased $69, or 0.8%, between 2004 and 2005. Our commercial operations segment benefited in this area largely due to reduced depreciation expense, as mentioned above, during 2005.

TriPath Oncology General and Administrative. General and administrative expenses incurred by the TriPath Oncology segment increased $345, or 7.7% between 2004 and 2005, from $4,486 to $4,831. This increase largely reflected the net increases as described above under *Total General and Administrative* with the exception of the reduced depreciation expenses.

Operating Income/Loss

Total Operating Income. Operating income during 2005 was $6,179, a $5,845 improvement compared with operating income of $334 in 2004. The improvement in operating income largely reflects incremental gross profit on new sales of reagents. Total increases in gross profit contributed $12,652 to the net improvement in operating income in 2005, compared with 2004. The increase in gross profit was partially offset by an increase in operating expenses of $6,807 or 14.5%, as described above.

Commercial Operations Operating Income. Operating income during 2005 attributable to Commercial Operations was $22,075, a $7,331, or 49.7%, improvement from operating income of $14,744 in 2004. The improvement in operating income largely reflects incremental gross profit on new sales of reagents. Total increases in gross profit contributed $12,386 to the net improvement in operating income in 2005, compared with 2004. The increase in gross profit was partially offset by an increase in operating expenses of $5,055, or 15.8%, as described above.

TriPath Oncology Operating Loss. Operating loss during 2005 attributable to TriPath Oncology was $15,896, a $1,486, or 10.3%, larger operating loss compared with $14,410 in 2004. The larger net operating loss reflects increased operating expenses of $1,752, or 11.8%, as described above, offset in part by increased gross profit of $266, or 55.0%, attributable mainly to fee per use revenues and sales of reagents.

Interest Income and Expense

Total Interest Income and Expense. Interest income for 2005 was $605, a $316, or 109.3%, increase from $289 earned during 2004, primarily attributable to higher average cash and cash equivalents balances in 2005 and to an environment of rising interest rates throughout 2005. The higher average cash and cash equivalent balances reflect our net increase in cash and cash equivalents balances, as we did generate positive cash flow during all four quarters of 2005 for the first time in our history. Interest expense for 2005 was $9 compared to $18 during 2004, a decrease of 50.0%.

Income Taxes

Total Income Taxes. Although we recorded net income in during 2005, we had consolidated losses for regular federal income tax purposes in all periods presented, as a result of accumulated net operating losses, thus requiring no provision for regular federal income taxes. Due to limitations in the carry forward of net operating losses for alternative minimum taxes, we recorded federal alternative minimum income tax and foreign and state income taxes of $275 in 2005 versus none in 2004. See "Critical Accounting Policies — Income taxes and valuation allowances" below for an explanation of our net operating loss carryforwards.

Net Income

Total Net Income. We recorded net income in 2005 of $6,500, which compares with net income of $605 in 2004, and improvement of $5,895, or 974.4%.

Years ended December 31, 2004 and 2003

The table below summarizes our segment results for the years ended December 31, 2004 and 2003. All intersegment revenues have been eliminated. Comments made throughout this discussion related to our segments refer to the figures in these tables:

	Commercial Operations			
	2004	2003	Change vs 2003	% Change
		(In thousands)		
Revenues	$67,862	$53,631	$14,231	26.5%
Cost of revenues	21,072	18,361	2,711	14.8%
Gross profit	46,790	35,270	11,520	32.7%
Operating expenses:				
Research and development	2,005	2,319	(314)	(13.5)%
Regulatory	3,263	4,763	(1,500)	(31.5)%
Sales and marketing	18,126	17,318	808	4.7%
General and administrative	8,652	7,264	1,388	19.1%
	32,046	31,664	382	1.2%
Operating income	$14,744	$ 3,606	$11,138	308.9%

	TriPath Oncology			
	2004	2003	Change vs 2003	% Change
		(In thousands)		
Revenues	$ 642	$ 133	$ 509	382.7%
Cost of revenues	158	16	142	887.5%
Gross profit	484	117	367	313.7%
Operating expenses:				
Research and development	9,275	6,542	2,733	41.8%
Regulatory	619	671	(52)	(7.7)%
Sales and marketing	514	1,006	(492)	(48.9)%
General and administrative	4,486	4,423	63	1.4%
	14,894	12,642	2,252	17.8%
Operating loss	$(14,410)	$(12,525)	$(1,885)	15.0%

Revenues

Total Revenues. Total revenues for the year ended December 31, 2004 were $68,504, a 27.4% increase from revenues of $53,764 for 2003. Compared with 2003, this net increase in total revenues was primarily due to (i) an increase in reagent sales of $13,669, or 35.0%, (ii) a net decrease in instrument sales of $499, or 6.6%, (iii) a net increase of $1,061 in other revenues, which consisted primarily of fee-per-use sales, service on system placements and freight and (iv) an increase in revenues recorded at TriPath Oncology of $509.

Commercial Operations Revenues. Revenues for the year ended December 31, 2004 from the Commercial Operations segment were $67,862, a 26.5% increase from revenues of $53,631 for 2003. In 2004, reagent sales increased $13,669 worldwide compared with 2003. Domestic sales of our SurePath and PrepStain reagents increased $10,117, or 33.3%, while international sales increased $3,552, or 41.3%. As a percentage of total revenues, reagent and disposable sales increased from 72.6% in 2003 to 76.9% in 2004. Worldwide we acquired in excess of 80 new SurePath laboratory customers, 37 in the U.S. Net realized revenue per test in 2004 decreased domestically 5% from 2003. This resulted from a decline in average price per test that was predominantly attributable to a shift in our revenue mix as a significantly larger percentage of revenues resulted from sales to the large commercial laboratory segment in the U.S. The large commercial laboratory segment accounted for 24.1% of all SurePath cervical cytology test kits sold in the U.S. in 2004 as compared to 16.1% in 2003. The increase in business from large commercial laboratory customers is a result of our growing relationships with Quest Diagnostics, LabCorp, AmeriPath and LabOne (recently acquired by Quest Diagnostics) and increasing focus of our sales and marketing efforts on the large commercial laboratory segment. As we shifted our focus to the large commercial laboratory segment, we did experience a deceleration in the rate of growth of our traditional and more fully penetrated customer base. Our SurePath Test Pack's share of the domestic Pap smear testing market in the U.S. was approximately 15% at the end of 2004 versus approximately 12% at the end of 2003.

Sales of instruments decreased $499, or 6.6%, during 2004 compared to 2003. Worldwide sales of PrepStain instruments for preparation of thin-layer slides for the SurePath liquid-based Pap test decreased by $1,105, or 32.0%, during 2004, including a domestic decrease of $281, or 32.8%. Revenues related to the sale of PrepStain instruments decreased $824, or 31.8%, internationally compared with 2003. This decrease occurred most notably in England as a significant number of instruments were acquired in 2003 by our distributor in anticipation of the UK's adoption of liquid-based Pap methodology. We placed 76 PrepStain instruments in the U.S., 66 under reagent rental agreements, and 46 outside the U.S., 2 under reagent rental agreements, during 2004. This compares with 103 PrepStain units placed in the U.S., 87 under reagent rental agreements, and 64 units placed outside the U.S., 2 under reagent rental agreements, in 2003. Worldwide sales of FocalPoint systems increased $507 during 2004. In the U.S., revenues generated from the sale of FocalPoint systems decreased $917 while revenues generated from fee-per-use agreements increased $296 (revenues generated from fee-per-use agreements are considered Other Revenue). The 2003 FocalPoint system revenues included non-recurring revenues from a large sale of instruments to Kaiser Permanente. Revenues generated from the sale and rental of FocalPoint systems outside the U.S. increased $1,424, primarily due to increased sales in Europe. In 2004, we placed 11 units net of returns in the U.S., 5 under fee-per-use agreements net of returns, and sold 10 units outside the U.S. This compares with 17 units in the U.S., 11 under fee-per-use agreements, and 4 units sold outside the U.S., in 2003. In 2003, 27 units were returned in total, of which 25 were from U.S. customers, as part of our ongoing efforts to rationalize the use of systems originally placed for screening of conventional Pap smears. Revenues recorded for SlideWizard system sales increased $99 between 2004 and 2003. We placed 13 SlideWizard units in 2004 compared with 8 in 2003.

Other revenues, consisting primarily of fee-per-use sales, service on system placements, and freight increased $1,061 during 2004. FocalPoint fee-per-use revenues increased $296 in 2004 compared to 2003, while service revenues worldwide increased $811 over 2003. Freight revenues also increased $203 from 2003 to 2004. Other net decreases were $249.

TriPath Oncology Revenues. Revenues recorded at TriPath Oncology increased $509 from $133 in 2003 to $642 in 2004, an increase of 382.7%. This increase is largely attributable to $500 of non-recurring revenues recorded in 2004 and resulted primarily from an imaging related fee resulting from the sale of an imaging research system.

Gross Margin

Total Gross Margin. Gross margin improved from 65.8% in 2003 to 69.0% in 2004. Our Commercial Operations segment was primarily responsible for the increase in gross margin because of continued growth in higher margin reagent and disposable sales and lean-based efficiencies in our manufacturing operations, which includes tools such as Value Stream Mapping, One-Piece Flow, Kanban Materials Management and Kaizen implementation methodology. Additionally, TriPath Oncology recorded increased gross margin due to a non-recurring imaging related fee.

Commercial Operations Gross Margin. Gross margin in our Commercial Operations segment improved from 65.8% in 2003 to 68.9% in 2004. Gross margin increased as the result of continued growth in higher margin reagent and disposable sales and lean-based efficiencies in our manufacturing operations, as mentioned above.

TriPath Oncology Gross Margin. Gross margin in our TriPath Oncology segment was 88.0% in 2003 compared with 75.4% in 2004. The gross margin recorded in our TriPath Oncology segment in 2003 had minimal impact on the overall gross margin due to the relatively small amount of gross profit contribution. The gross margin recorded in 2004 was primarily attributable to non-recurring revenues and resulted primarily from an imaging related fee resulting from the sale of an imaging research system.

Research and Development

Total 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 2004 were $11,280, a 27.3% increase from $8,861 in 2003.

Commercial Operations Research and Development. Our Commercial Operations segment incurred research and development expenses of $2,319 and $2,005 in 2003 and 2004, respectively, a decrease of 13.5%. Research and development expenditures relating to our Commercial Operations segment reflect research activity related to our cervical cytology product line and the development of manufacturing capabilities for new molecular tests that we are developing.

TriPath Oncology Research and Development. Our TriPath Oncology segment incurred research and development expenses of $6,542 and $9,275 for 2003 and 2004, respectively, an increase of 41.8%. These expenditures reflected the redirection of 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. The increase in expenses incurred in 2004 versus 2003 largely reflects the loss of the amortization of a deferred credit that we had been recording as an offset to research and development expense over the 30 months ended January 2004, when this credit expired. Whereas 2003 contained a credit of $2,479 offset against research and development expenses, 2004 reflected only $207 of this expense credit, resulting in an increase to expenses of $2,272 related to this item. The balance of the net increase in these expenses was related to the acceleration of efforts on our existing molecular diagnostic programs.

Regulatory

Total 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, 2004 were $3,882, representing a 28.6% decrease from $5,434 in 2003.

Commercial Operations Regulatory. Regulatory expenses were $3,263 in the Commercial Operations segment in 2004, compared with $4,763 in 2003, a decrease of $1,500, or 31.5%. This reduction in regulatory expense primarily reflected the winding down of clinical trials, in particular, the FocalPoint GS and HPV related clinical trials that were initiated in 2003. In addition, costs were higher in 2003 as the result of activities related to the European IVDD compliance initiatives.

TriPath Oncology Regulatory. There were $619 of regulatory expenses incurred by the TriPath Oncology segment in 2004 versus $671 in 2003. This modest decrease was in part due to the fact that our efforts to complete several clinical trials in our Commercial Operations segment were our primary focus at the time.

Sales and Marketing

Total 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 2004 were $18,640. This represented a 1.7% increase from $18,324 in 2003.

Commercial Operations Sales and Marketing. Sales and marketing expenses for 2004 incurred by the Commercial Operations segment were $18,126. This represented a 4.7% increase from $17,318 in 2003. This year-over-year increase predominantly reflects the beginning of our sales force expansion in the third quarter of 2004 and to the reintroduction of a number of targeted marketing programs during late 2003 and the first half of 2004.

TriPath Oncology Sales and Marketing. Sales and marketing expenses for 2004 incurred by the TriPath Oncology segment were $514. This represented a 48.9% decrease from $1,006 in 2003 and was largely attributable to a redirection of efforts aimed to support the early stage reorganization and expansion of our sales and marketing activities targeted primarily towards our pursuit of additional business under our agreements with large commercial laboratories, as well as in anticipation of the launch of our future molecular diagnostic products.

General and Administrative

Total 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 $13,138 in 2004 compared with $11,687 in 2003. This reflects a net increase of $1,451, or 12.4%, between 2003 and 2004 and is largely attributable to increases in costs related to professional fees, principally litigation and costs incurred to comply with the requirements of Section 404 and 302 of the Sarbanes-Oxley Act of 2002 (which relate to internal controls over financial reporting and certification of disclosure), corporate insurance, and consulting fees. These increases were offset somewhat by lower personnel-related expenses, including lower incentive compensation expenses, and a lower provision for doubtful accounts. Professional fees increased by $1,889 between 2003 and 2004, largely attributable to litigation costs. We recorded increases in corporate insurance costs between 2004 and 2003 of $154, while costs related to Board of Director fees increased $126. In total, these expenses increased by about $2,169. Personnel-related costs decreased in 2004 by $600. Additionally, we experienced a decrease in our provision for doubtful accounts of $180 from 2003 to 2004. Other net increases and decreases were individually, and collectively, insignificant.

Commercial Operations General and Administrative. General and administrative expenses incurred by the Commercial Operations segment increased $1,388, or 19.1% between 2003 and 2004, from $7,264 to $8,652. This increase is largely attributable to increases in costs related to professional fees, principally litigation and costs incurred to comply with the requirements of Section 404 and 302 of the Sarbanes-Oxley Act of 2002, corporate insurance, and consulting fees as discussed above. Also, as discussed above, these increases were offset somewhat by lower personnel-related expenses and a lower provision for doubtful accounts.

TriPath Oncology General and Administrative. General and administrative expenses incurred by the TriPath Oncology segment increased $63, or 1.4% between 2003 and 2004, from $4,423 to $4,486. This increase largely reflected increases in professional fees and costs incurred to comply with requirements of Section 404 and 302 of the Sarbanes-Oxley Act of 2002 and insurance costs offset by decreases in personnel-related incentive expenses.

Operating Income/(Loss)

Total Operating Income/(Loss). Operating income from operations during 2004 was $334, a $9,253 improvement compared with an operating loss of $8,919 in 2003. The improvement in operating income largely reflects incremental gross profit on new sales of reagents. Total increases in gross profit contributed $11,887 to the

net improvement in operating income in 2004, compared with 2003. The increase in gross profit was partially offset by an increase in operating expenses of $2,634 or 5.9%, as described above.

Commercial Operations Operating Income. Operating income during 2004 attributable to Commercial Operations was $14,744, an $11,138, or 308.9%, improvement from operating income of $3,606 in 2003. The improvement in operating income largely reflects incremental gross profit on new sales of reagents. Total increases in gross profit contributed $11,520 to the net improvement in operating income in 2004, compared with 2003. The increase in gross profit was partially offset by an increase in operating expenses of $382, or 1.2%, as described above.

TriPath Oncology Operating Loss. Net operating loss during 2004 attributable to TriPath Oncology was $14,410, a $1,885, or 15.0%, larger operating loss compared with $12,525 in 2003. The larger net operating loss reflects increased operating expenses of $2,252, or 17.8%, as described above, offset in part by modest gross profit, attributable mainly to a non-recurring imaging-related fee of $367.

Interest Income and Expense

Total Interest Income and Expense. Interest income for 2004 was $289, a 30.0% decrease from the $413 earned during 2003, primarily attributable to lower average cash and cash equivalents balances in 2004. The lower average cash and cash equivalent balances reflected our net decrease in cash and cash equivalents balances averaged $167 per month during 2004, though we did generate positive cash flow during both the third and fourth quarters of 2004 for the first time in our history. Interest expense for 2004 was $18, compared to $32 during 2003. This decrease was due to reduced balances outstanding resulting from principal repayments under our debt facilities.

Net Income/(Loss)

Total Net Income/(Loss). We recorded net income in 2004 of $605 which compares with a net loss of $8,538 in 2003, an improvement of $9,143, or 107.1%. Although we recorded net income in 2004, we had consolidated federal income tax losses in all periods presented, due to accumulated net operating losses. See "Critical Accounting Policies — Income taxes and valuation allowances" below for an explanation of our net operating loss carryforwards.

Liquidity and Capital Resources

Since our formation and until 2004, our expenses had significantly exceeded our revenues, resulting in an accumulated deficit of $225,915 as of December 31, 2005. We have funded our operations primarily through the private placement and public sale of equity securities, debt facilities and product sales resulting in cumulative net proceeds of $371,061 as of December 31, 2005. We had cash and cash equivalents of $22,457 at December 31, 2005.

We funded our operations in 2005 from cash and cash equivalents on hand and revenues from both our Commercial Operations and TriPath Oncology segments.

The table below summarizes certain key components of our cash flow and working capital for 2005, 2004 and 2003, as well as changes between 2005 and 2004 and changes between 2004 and 2003. Comments made throughout this discussion refer to the figures in this table.

				2005 vs. 2004		2004 vs. 2003	
	2005	2004	2003	$ Change	% Change	$ Change	% Change
				(In thousands)			
Cash Flow Type							
Operating	$ 4,553	$(1,900)	$(12,534)	$6,453	339.6%	$10,634	(84.8)%
Investing	(1,612)	(1,541)	50	$ (71)	4.6%	$(1,591)	(3,182)%
Financing	836	1,186	843	$ (350)	(29.5)%	$ 343	40.7%
Cash and cash equivalents	22,457	18,949	20,954	$3,508	18.5%	$(2,005)	(9.6)%

Operating

2005 versus 2004

Cash provided by operating activities was $4,553 during 2005, compared with net cash used of $1,900 during 2004, an improvement of $6,453. This improvement in net cash provided by operations versus net cash used in operations was largely attributable to improved operating performance. We recorded net income of $6,500 for 2005 compared with $605 for 2004, an improvement of $5,895. This improvement in earnings was augmented by a further $558, comprised of an increase in non-cash items of $1,043 offset by a net increase of $485 in the use of cash in operating assets and liabilities between 2004 and 2005.

The increase in non-cash items of $856 between 2005 and 2004 was primarily due to an increase in non-cash sales discount of $759 and an increase of $297 in depreciation. Amortization of deferred research and development credits decreased by $207 and we and we reduced our reserve for obsolete and slow-moving inventory by $383. Other net increases amounted to $163.

The net increase of $485 in the use of cash in operating assets and liabilities between 2004 and 2005 was primarily affected by a reduction in working capital applied to accounts payable and accrued expenses of $6,830 offset by an increase in working capital applied to accounts receivable and notes receivable and net investments in sales-type leases of $3,668 and inventory of $2,353. The reduction in working capital applied to accounts payable and accrued expenses was primarily attributable to personnel-related expenses, inventory purchases and clinical trial-related payments. The increase in working capital applied to accounts and notes receivable and net investments in sales-type leases was attributable to increased revenues and the increase in working capital applied to inventory was attributable to investments in inventory, including customer use assets. Additional working capital was also applied to increased prepaid items and other assets of $804. Other changes in operating assets and liabilities reflected a net use of cash of $490.

2004 versus 2003

Negative operating cash flow during 2004 was caused in large part by investments in customer use asset placements of $3,728, included in inventory changes, and reductions in accounts payable and accrued expenses of $4,521. These uses of cash were partially offset by non-cash items, primarily depreciation of $4,097, amortization of intangible assets of $841 and amortization of non-cash sales discount of $519. Additionally, we generated net income of $605 in 2004. Negative operating cash flow during 2003 was caused primarily by operating losses of $8,538 and the settlement of a contingent liability of $2,410. The net improvement in cash used in operations between 2004 and 2003 was $10,634 and was largely attributable to improved earnings (reduced net loss) of $9,143 from 2003 to 2004. This improvement in earnings was augmented by a further $1,491, comprising an increase in non-cash items of $2,807, offset by an increase of $1,316 in the use of cash in operating assets and liabilities between 2003 and 2004. The increase in non-cash items of $2,807 was primarily due to an increase in depreciation of $558, amortization of non-cash sales discount of $519, and a decrease in the amortization of deferred research and development credits of $2,272. The primary factors affecting the increase in the use of cash in operating assets and liabilities between 2003 and 2004 were decreases in accounts payable and accrued expenses of $8,448, primarily attributable to decreased incentive compensation and clinical trial accruals, offset by funding from accounts receivable, notes receivable and net investments in sales-type leases of $3,424, as we held receivables essentially flat in 2004 in spite of increasing revenues, and $2,410 attributable to the payment of an amount in settlement of a contingent liability in 2003.

Investing

Cash used in investing activities in 2005 was $1,612 compared with cash used in investing activities of $1,541 in 2004 and cash provided by investing activities of $50 in 2003. Our capital expenditures were $1,588 in 2005, $1,215 in 2004, and $146 in 2003, with expenditures primarily attributable to the purchase of machinery and equipment. We have no material commitments for future capital expenditures. During 2004 we added $319 to intangible assets versus $24 in 2005, a decreased use of cash of $295. In 2004, we acquired rights to certain intellectual property in connection with our work at TriPath Oncology for an initial payment of $319.

Financing

2005 versus 2004

Our cash provided by financing activities for 2005 decreased by $350, or 29.5%, compared to 2004, from $1,186 to $836. These cash flows were most impacted by debt activity and stock option exercises. We had no borrowings during 2005 versus $365 during 2004. Additionally, we received less cash from stock option exercises and common stock issued under our employee stock purchase plan in 2005 versus 2004 by $346. Partially offsetting these reductions of cash from financing activities were lower payments on debt and leases in 2005, where we paid $361 less in 2005 than in 2004.

2004 versus 2003

Our cash provided by financing activities for 2004 increased by $343, or 40.7%, compared to 2003, to $1,186 from $843. These cash flows were most impacted by debt activity and stock option exercises. We had $633 of borrowings during 2003 versus $365 during 2004. Additionally, we received less cash from stock option exercises and common stock issued under our employee stock purchase plan in 2004 versus 2003 by $379. Offsetting these reductions of cash from financing activities were lower payments on debt and leases in 2004, where we paid $990 less in 2004 than in 2003.

Litigation

We compete with Cytyc Corporation (Cytyc) with respect to the sale of our FocalPoint and Cytyc's sale of its ThinPrep Imaging System. We believe Cytyc's ThinPrep Imaging System infringes our patents. In 2003 we filed a lawsuit seeking damages and injunctive relief to stop such infringement and, Cytyc filed a separate action seeking a declaratory judgment in their favor. On January 5, 2004, those suits were consolidated into a single action in the United States District Court for the District of Massachusetts. The case numbers for the consolidated action are 1:03-CV-12630-DPW and 1:03-CV-11142-DPW. The case numbers are for reference only and the corresponding pleadings are expressly not incorporated into this document by reference. Fact and expert discovery have been completed. A claim construction or Markman ruling was issued by the court on November 28, 2005. The court has entered a scheduling order setting forth certain deadlines through June 2006, including those for conducting mediation and filing of summary judgment motions. We anticipate that a trial will be scheduled sometime in late 2006 or the first half of 2007. We are unable to predict the ultimate outcome. Similarly, we are unable to predict the potential effect on our business and results of operations that any outcome may ultimately have.

Financing Arrangements

In January 2005, we renewed our $7,500 working capital facility with Silicon Valley Bank. We also extended the term of the line of credit to 15 months with an expiration date of April 27, 2006. The entire amount of the line is available as long as certain financial covenants are met. If these covenants are not met, the available balance is limited to an amount equal to 80% of eligible accounts receivable. At December 31, 2005, we were entitled to borrow the full amount of the line, less amounts secured by the letter of credit referred to below. The renewed line offers either a prime-based (prime plus 0.25%) or LIBOR-based (LIBOR plus 2.0%) pricing option for advances made under it 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, 2005, though the availability under the line of credit could provide additional funding if needed.

In April 2003 we obtained a one-year commitment for a $2,500 lease line of credit with General Electric Capital Corporation (GE Capital). This commitment, which carried three-year lease terms for items acquired under it, was used to secure operating leases for assets, primarily equipment. In March 2004, this line was renewed for $2,000 (in addition to amounts for assets already leased under the line). Terms of the new line were substantially the same as the expiring line. The primary difference is that lease terms under the new line range from 30 to 36 months. The interest rates on the various schedules under this lease line range from 2.85% to 3.45%. As of December 31, 2005, assets with an original cost of $1,917 were leased under this lease line. Future minimum lease payments under this lease line are $1,023.

During August 2002, we secured a $1,500 lease line of credit from Bank of America. Bank of America assigned the leases under this line to GE Capital in 2004. This line is secured by a letter of credit against our line of credit with Silicon Valley Bank in the amount of $424 (see Note 5 to the Condensed Consolidated Financial Statements). 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. The interest rates on the various schedules under this lease line range from 2.75% to 2.90%. As of December 31, 2005, assets with an original cost of $1,286 were leased under this lease line. As this line has expired, no further assets will be leased under this line of credit. Future minimum lease payments under this lease line are $345.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities which we cannot reasonably predict future payment. The following chart represents our contractual obligations, aggregated by type (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating and capital lease obligations	$11,949	$2,252	$2,557	$1,499	$5,641
Total contractual obligations	$11,949	$2,252	$2,557	$1,499	$5,641

Off-Balance Sheet Arrangements

We have no other long-term debt commitments and no off-balance sheet financing vehicles.

Outlook
(amounts in thousands, except per share amounts)

Our success in 2006 will depend on our ability to continue to take advantage of the opportunities for growth that we have created over the past five years, our ability to balance the costs associated with effective research, development, and marketing and selling programs with revenue growth, and the extent to which we can continue to leverage our operating infrastructure.

We estimate that full year revenues for 2006 will be in the range of $102,000 to $105,000 and will reflect continued growth in our cervical cytology business as well as revenues generated from the early commercialization of some of our molecular diagnostic reagents and molecular imaging systems. Revenues for any particular period will depend upon the timing of certain remaining deferred sales discounts that we would amortize over a six-month period if and when it becomes probable that any of two currently unexercisable tranches of warrants held by Quest Diagnostics may vest upon achievement of certain sales-based milestones. Quest Diagnostics earned the warrants under two of the four sales-based milestones in 2005, leaving two to be earned in future periods. While not certain, it is possible that certain sales-based milestones for these two tranches of warrants will be achieved by Quest Diagnostics that, if met, will result in additional non-cash sales discounts of up to $1,619 in 2006.

We expect that our growth in revenues in 2006 will be primarily driven by the sale of reagents and disposables as well as growth from the sum of sales, rentals and usage fees derived from new and existing placements of our instruments. We expect that revenues from our cytology products will grow approximately 18% to 20% and that revenues generated from some of our molecular reagents and interactive histology imaging system will increase by approximately 100% from 2005.

Given our anticipated revenue mix, we expect that our gross margins will fall into a range of between 67% and 70% in 2006. As we continue our focus on the large commercial laboratory segment, we expect to continue to face a corresponding deceleration in the relative growth of business within our traditional and more fully penetrated customer base. As sales to large commercial laboratories continue to increase, there may be some downward pressure on gross margin as the selling prices of our tests to higher volume customers, such as these large commercial laboratories, tend to be lower than selling prices to our other laboratory customers. We anticipate this downward trend may be somewhat offset as continued improvements to our manufacturing costs, due to higher

volumes and efficiencies from our lean-based manufacturing programs, continue to favorably impact cost of goods sold. The extent to which gross margin is affected as the result of this trend will depend upon the relative number of tests sold to the higher volume laboratories at any point in time.

The structure of our agreement with Ventana relating to the sale of a Ventana branded version (VIAS) of our interactive histology imager may also impact our gross margin in 2006. Pursuant to the agreement we will receive a fixed payment for each imager manufactured for Ventana and usage fees for each Ventana test processed on each imaging system after placement with a Ventana customer. The instrument transfer price includes a small premium over our cost of manufacture and, as a result, will generate a gross margin for each instrument sold that is lower than is typical for our instrument sales. The anticipated gross margin associated with the usage fees approaches 100%. Since most of the activity in the first year of this agreement will logically relate to the initial placement of imaging systems, we anticipate that most revenues generated from this relationship in the first half of 2006 will reflect the lower gross margin associated with the instrument transfer price. We expect that this downward trend will be offset by the higher gross margin generated over time from usage fees, which we anticipate will become more significant during the latter half of 2006. The extent to which the overall gross margin is affected will depend on the extent to which Ventana is successful in placing instruments and generating tests from each instrument placed.

We expect our operating expenses to increase in 2006 by 15% to 20% from those from those reported in 2005. The most significant increase in operating expenses that we expect in 2006 will occur in our regulatory and clinical affairs programs. We expect that these expenses will increase by $6,500 to $7,000 in 2006 as we invest in our breast cancer staging and cervical screening (SurePath Molecular Pap test) clinical trials and collect additional data in support of a resubmission to the FDA relating to our FocalPoint GS Imaging System. We expect that expenses related to our clinical trials will be greatest in the first half of 2006 and will begin to decline in the third quarter. As we have transitioned our molecular imaging system, our breast cancer staging assay, and the SurePath Molecular Pap test either into the market place or into clinical trials, we have completed a number of development activities related to these products. We therefore expect to reduce research and development costs by approximately 10% in 2006. We expect that the impact of the actions taken in January 2006 related to the completion of these development activities will result in cost reductions beginning in the second quarter as, termination costs related to these cost reductions will principally be reflected in the first quarter of 2006. We expect that sales and marketing expenses will increase by approximately 15% to 20% in 2006 as we experience the full-year impact of the expanded sales and marketing activities that we implemented in 2005. We expect that general and administrative expenses will be comparable to those recorded in 2005.

Our Commercial Operations segment has been profitable for over three years and generated operating income of $22,075 in 2005, an increase of 49.7% over 2004. We expect that this segment will continue to generate significant operating income and cash. The excess cash flow generated from the Commercial Operations segment has been, and will continue to be utilized in part to fund the operations of our TriPath Oncology segment. We anticipate that the TriPath Oncology segment, which includes all research and development, regulatory, sales and marketing, and administrative expenses relating to our molecular diagnostic programs, will incur $1,500 to $2,000 of expenses per month during 2006 as we engage in clinical trials with respect to our cervical screening and breast staging assays, generate internal and external research studies on our RUO reagents for ovarian screening, select a multiplexing testing platform for our blood based screening assays that will allow for simultaneous detection of multiple markers from a very small volume of blood, adapt our ovarian screening assay to this testing platform in advance of anticipated clinical trials in 2007, introduce Class I IHC kits that incorporate our Pro Ex C biomarkers, and expand the VIAS testing menu.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)", which is a revision of FASB Statement No. 123, "Accounting for Stock-Based Compensation." The adoption of SFAS 123(R)'s fair value method will have an impact on our results of operations, although it will have no impact on our overall financial position or overall cash flow. The impact of adoption of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of Pro forma net loss and loss per share in footnote 2 (Stock Based Compensation) of our financial statements. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current

literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We adopted this Standard as of January 1, 2006 and will use the modified prospective application transition method. Our current estimate for the non-cash impact of implementing FAS 123(R) on existing stock-based compensation instruments is less than $0.01 per share for full year 2006. However, if we issue annual grants of stock-based compensation instruments during 2006, as we typically do around the time of our annual shareholders' meeting in May, there will be additional impact on our earnings per share. Since the majority of our outstanding options were vested in 2005 or prior, our current estimate of the total stock-based compensation expense in 2006, if stock-based compensation is granted, is an impact to earnings per share of between $0.01 and $0.02 per share, principally during the second half of 2006. This is discussed further below under "Recently Issued Accounting Standards."

We believe that we can continue to manage our cash to minimize the need for additional outside sources of cash in 2006. For the second straight year, we experienced positive cash flow from the business during 2005. While our positive cash flow is an important milestone, we may experience one or two additional quarters of negative cash flow in any given period, but we anticipate generating positive cash flow for the full year 2006 as a whole and beyond. We expect that our capital expenditures for 2006 may range from $1,000 to $1,500. We may borrow from our line of credit with Silicon Valley Bank to finance part, or all, of those capital expenditures. While the line is set to expire in April 2006, we have no reason to believe the line will not be renewed for another twelve-month term. We have remaining availability under a commitment for a $1,000 lease line of credit that will be utilized for equipment placed under operating leases. We believe that our existing cash, our expectation of continuing to generate positive cash flow for the full-year 2006, anticipated additional debt and/or lease financing for internal use assets, rental placements of PrepStain and fee-per-use placements of FocalPoint instruments will be sufficient to enable us to meet our future cash obligations for at least the next 12 months.

While it is expected that marketing and sales expenditures for the continued SurePath commercial rollout for gynecological uses in the United States will increase, and it is possible that, 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 allow us to avoid raising additional funds for operating purposes in the near future. If, however, our existing resources prove insufficient to satisfy our liquidity requirements, or if we need cash for any non-routine purpose, we may need to raise additional funds through bank facilities, the sale of additional equity or debt securities or other sources of capital. In addition, we may opportunistically take advantage of favorable conditions in the capital markets and raise debt or equity publicly if such conditions are present and such financing is advisable. The sale of any equity or debt securities, if required, may result in additional dilution to our stockholders. We cannot be certain that additional financing will be available in amounts, or on terms, acceptable to us, if at all. Our failure to participate in such financing, if needed, could have a material adverse effect on our liquidity and capital resources, business, financial condition and results of operations.

Certain Factors Which May Affect Future Operations and Results

This Management's Discussion and Analysis contains certain 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, including those described below that could cause actual results to differ from those projected. The forward-looking statements include those made in the section entitled "Outlook" above, as well as statements about our: projected timetables for the pre-clinical and clinical development of, regulatory submissions and approvals for, and market introduction and commercialization of our products and services; advancement of TriPath Oncology's product development programs; expected future revenues, profitability, margins, operations and expenditures; sales and marketing force expansion; anticipated progress in the large commercial laboratories and projected cash needs. We caution investors not to place undue reliance on the forward-looking statements contained in this report, which speak only as of 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 increase sales and revenues at our historical rates;
- we may not receive revenues when or in the amounts anticipated;
- we may not be able to maintain profitability;
- we may have to reflect non-cash sales discounts in connection with warrants held by Quest Diagnostics for different financial periods than we expect, depending upon if and when it becomes probable that certain sales-based milestones may be met in connection with our agreement with Quest Diagnostics;
- we may not be able to increase our penetration of the very competitive large commercial laboratories to the extent we expect, and we may not be able to maintain and grow our business within our traditional customer base to the extent we expect;
- we may not achieve revenues to the degree expected from our relationship with Ventana and the sale of analyte-specific reagents and research use only products derived from our molecular oncology development program;
- our expanded sales and marketing presence may not have the expected impact, and we may face attrition issues customary for such an expansion;
- we may incur greater expenses than we expect generally and with our clinical trials and sales and marketing efforts specifically;
- our clinical trials may take longer to complete than we expect and may be unsuccessful;
- we may not receive FDA approval for our FocalPoint GS and HPV-related applications;
- we may not receive FDA clearance for processing additional Ventana assays on the interactive histology imager on schedule or at all, and we may be required to obtain additional FDA and other regulatory approvals for the interactive histology imager, along with approvals for processing the assays, which we may not receive in a timely manner or at all;
- revenues from our agreement with Ventana may not materialize to the extent we expect;
- we may not be successful in selling TriPath Oncology's pre-IVD (in-vitro diagnostic) products and services;
- sales of our stock by Roche Holdings, Inc., which owns approximately 20% of our stock, may significantly impact our stock price;
- we may need to obtain additional financing in the future;
- we may be unable to obtain and maintain adequate patent and other proprietary rights protection of our products and services;
- our products may not receive regulatory, pricing and reimbursement approval when we expect, if at all;
- we may be unable to comply with the extensive domestic and international governmental regulatory, pricing and reimbursement approval and review procedures and other regulatory requirements to which the manufacture and sale of our products are subject, or lack the financial resources to bear the expense associated with such compliance;
- our products may not be accepted by the market to the extent we expect and the frequency of use of our screening products may decline;
- TriPath Oncology may be unable to successfully develop and commercialize molecular diagnostic oncology products when anticipated, if at all;
- external studies of our product candidates may not come to the conclusions we expect;
- TriPath Oncology may be unable to license markers needed to optimize its product candidates;

- we may be unable to establish and maintain licenses, strategic collaborations and distribution arrangements;
- we and laboratories using our products may not obtain adequate levels of third-party reimbursement for our products;
- we may lack the financial resources necessary to further develop our marketing and sales capabilities domestically and internationally or to expand our manufacturing capability;
- competition and technological, scientific and medical, changes may make our products or potential products and technologies less attractive, used less frequently, or obsolete;
- our promotional discounts, sales and marketing programs and strategies may not have their expected effect; and
- uncertainties resulting from the initiation and continuation of our litigation with a competitor could have a material adverse effect on our ability to continue our operations.

Some of these factors and others are discussed in more detail in Exhibit 99.1 "Factors Affecting Future Operating Results" to this Annual Report on Form 10-K for the year ended December 31, 2005, which exhibit is incorporated into this report by reference.

Income Taxes and Tax Loss Carryforwards

We generated federal taxable income before carryforwards for the first time in 2005, but such income was completely offset by prior net operating loss carryforwards. We recognized current domestic income tax expense, however, as a result of limitations with respect to federal alternative minimum tax net operating loss carryforwards and insufficient state loss carryforwards to fully offset state taxable income. In 2003 and 2004, the effective tax rate was 0%. In 2005, the effective tax rate was 4.1%. The increase is due to alternative minimum tax and state taxes, as discussed above.

Realization of deferred tax assets is dependent on future taxable 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, 2005 and 2004.

At December 31, 2005, we had net operating loss carryforwards of approximately $211,928 for federal income tax purposes and approximately $91,550 for state income tax purposes. We also had approximately $2,429 in research and development credit carryforwards and $144 alternative minimum tax credit carryforwards. The federal and state net operating loss carryforwards have expiration periods that begin in 2007 and 2006, respectively, and end in 2024. The research and development credit carryforwards have expiration periods that begin in 2017 and end in 2025. The alternative minimum tax credit carryforward has no expiration date. Approximately $6,990 of the net tax loss carryforwards is attributed to deductions for stock options, the tax effect of which is credited to equity when recognized.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions, ownership changes with respect to a 1995 stock issuance and our 1999 merger with NeoPath, Inc. have resulted in the imposition of substantial annual limitations on our use of net operating losses and credit carryforwards attributable to periods before the changes.

Critical Accounting Policies

The preparation of our Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles (GAAP) in the U.S., requires us to make estimates and judgments that affect the reported amounts of assets and liabilities at the date of the financial statements; revenues and expenses as of the date reported; 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. Actual results may differ from these estimates under different assumptions.

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, 2005. 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 is the predominant vehicle for international instrument sales. If, however, we sell an instrument directly to an international end user, we record the revenue upon installation and acceptance of the instrument, consistent with our treatment 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, revenue recognition occurs at the time of shipment of the reagent kits or on a monthly basis based on the actual or minimum usage. There is no capital equipment revenue recognized under these transactions.

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 respond to customer needs by offering both capital and operating lease alternatives. Under the capital lease alternative, revenue is recognized initially as an instrument sale with part of the lease payments being allocated to interest income, and service revenues, if applicable, over the lease term. Under operating leases, we do not recognize any revenue related to the instrument sale, but recognize revenue as rental income over the lease term.

In 2004 we entered into an agreement that contained multiple elements with respect to revenue recognition. For that agreement, as well as any others that we may enter into in the future, we research the relevant authoritative literature related to the various elements contained within the agreement and document our interpretation of the relevant GAAP within the quarter we first recognize revenue from the agreement.

We consider the accounting policies regarding revenue recognition to be critical for several reasons. The first is 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. Further, as is typical with many companies that sell durable equipment, we often experience increased sales activity near, or at, the end of fiscal quarters. This requires us to closely examine each equipment sale to ensure the requisite terms have been met to allow revenue recognition under GAAP. Additionally, certain of our equipment sales contracts may contain terms that would grant certain "evaluation," or "free-use" periods, or terms that would allow the customer to return equipment. These terms, when present, are considered prior to our recording revenue. Finally, because of the multiple elements in one of our agreements, and the potential for additional agreements with multiple elements, we believe that the complexity of these agreements warrants a heightened scrutiny on the part of accounting and finance management.

Sales of consumable products are recorded at shipment. Billings and costs related to shipping products to customers are included in both revenues and cost of revenues, respectively.

Allowance for Doubtful Accounts

We continually monitor amounts due, and payments from our customers and maintain an allowance for doubtful accounts 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, we take into account various factors including our accounts and notes receivable and net investments in sales-type leases agings, customer credit-

worthiness, historical bad debts and current economic trends. We age receivables from customers based on contractual terms. From time to time, customers are slow in paying amounts due us.

We closely monitor 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. 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. If reimbursement from third party payors to our laboratory customers was to be reduced or otherwise changed substantially, our ability to collect outstanding accounts receivable could be impacted significantly as the laboratory would have to look to other sources (like the patient) for payment, and that could complicate the laboratory's billing and collection efforts by increasing the number, and decreasing the size, of customers from whom they would need to collect amounts. If a trade receivable ages past one year, our policy is to consider the receivable balance non-performing if there has been no measurable contact or dialogue with the customer. These receivables would typically be fully reserved for by this point. Once a receivable is classified as non-performing, then we consider whether to charge-off the receivable balance against our allowance for doubtful accounts. Factors that figure into this determination include the extent and nature of dialogue we have with the customer and whether the customer is still in business.

In assessing the adequacy of our allowance for doubtful accounts, finance management meets, typically once or twice monthly, with individuals responsible for collecting outstanding accounts and notes receivable and net investments in sales-type leases balances. Management reviews the work undertaken during the course of the month by those responsible for collections and guides activities for the following week's actions intended toward collections of outstanding accounts and notes receivable and net investments in sales-type leases. Accounts are discussed specifically, and to the extent they show potential for aging beyond acceptable limits, adjustments to our allowance for doubtful accounts are discussed and made. If required, accounts are placed on credit hold status to stimulate payments on aging accounts. We ensure the sales organization is aware of collection-related actions we take on individual accounts, including placing accounts on credit hold, so that they can intervene in the collection process as well.

At December 31, 2005 and 2004, our accounts receivable, notes receivable and net investments in sales-type leases, net of allowance for doubtful accounts of $1,324 and $1,262, respectively, was $18,798 and $14,796. See additional commentary under *"Liquidity and Capital Resources — Operating"* above for further discussion of our allowance for doubtful accounts and related bad debt expense.

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 overvalued inventory may be required.

Over half, approximately 57%, 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 2006. We had been recording additional expense during 2003 and 2004 to build a reserve for this inventory. After reviewing these factors during 2005, we reversed $308 of excessive reserves for obsolete and slow-moving inventory. We will continue to monitor inventory and related reserves during 2006.

At December 31, 2005 and 2004, our total inventory balance, net of reserves for obsolescence of $2,704 and $3,105, respectively was $12,564 and $10,723.

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 either 2005 or 2004.

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 2006. 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 long-lived and intangible assets 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.

Income taxes and valuation allowances

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. Due to cumulative tax losses prior to 2005 and the uncertainty of generating future taxable income, however, a valuation allowance equal to the amount of the net deferred tax assets has been established. We will evaluate and review the need to reduce the valuation allowance on a quarterly basis, primarily based on our estimates of future taxable income. Changes in our assessment of the need for a valuation allowance could give rise to a credit to income tax expense in the period of change except for the portion attributed to deductions for stock options which would be reflected as a direct increase to stockholder's equity.

At December 31, 2005, we had net operating loss carryforwards of approximately $211,928 for federal income tax purposes and approximately $91,550 for state income tax purposes. We also had approximately $2,429 in research and development credit carryforwards and $144 alternative minimum tax credit carryforwards. The federal and state net operating loss carryforwards have expiration periods that begin in 2007 and 2006, respectively, and end in 2024. The research and development credit carryforwards have expiration periods that begin in 2017 and end in 2025. The alternative minimum tax credit carryforward has no expiration date. Approximately $6,990 of the net tax loss carryforwards is attributed to deductions for stock options, the tax effect of which is credited to equity when recognized.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions, ownership changes with respect to a 1995 stock issuance and our 1999 merger with NeoPath, Inc. have resulted in the imposition of substantial annual limitations on our use of net operating losses and credit carryforwards attributable to periods before the changes.

We consider the accounting for income taxes to be critical for two primary reasons. First, the size of the valuation allowance is significant, and, second, utilization of net operating loss and credit carryforwards are subject to complex treatment under the Code and may expire unused.

Recently Issued Accounting Standards

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — an Amendment of ARB No. 43, Chapter 4" ("SFAS No. 151") to clarify the accounting for abnormal amounts of idle facility expense, freight,

handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges. . . .". SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier adoption permitted. The provisions of SFAS No. 151 shall be applied prospectively. We adopted this Standard as of January 1, 2006 and the adoption did not have a material impact on our consolidated financial statements.

In December 2004, the FASB issued Statement No. 153, "Exchanges of Nonmonetary Assets — an amendment of APB Opinion No. 29" ("SFAS No. 153"). SFAS No. 153 addresses the measurement of exchanges of nonmonetary assets. The guidance in APB Opinion No. 29, "Accounting for Nonmonetary Transactions", is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. SFAS No. 153 amends APB Opinion No. 29 to eliminate the exception of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for financial statements for fiscal years beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges incurred during fiscal years beginning after the date this Statement is issued. We do not expect the adoption of SFAS No. 153 to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Share Based Payment" ("SFAS No. 123(R)"). SFAS No. 123(R) is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123(R) eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements using a fair value-based method. SFAS No. 123(R) was to be effective as of the beginning of the first interim period that began after June 15, 2005. In April of 2005, the U.S. Securities and Exchange Commission ("SEC") announced that it would delay the effective date for financial statement compliance with SFAS No. 123(R) until the first annual reporting period of the registrant's first fiscal year beginning after June 15, 2005. We adopted this Standard as of January 1, 2006 and will use the modified prospective application transition method. Our current estimate for the non-cash impact of implementing FAS 123(R) on existing stock-based compensation instruments is less than $0.01 per share for full year 2006. However, if we issue annual grants of stock-based compensation instruments during 2006, as we typically do around the time of our annual shareholders' meeting in May, there will be additional impact on our earnings per share. Our current estimate of the total stock-based compensation expense in 2006, if stock-based compensation is granted, is an impact to earnings per share of between $0.01 and $0.02 per share, principally during the second half of 2006.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations — an interpretation of SFAS No. 143" ("FIN No. 47"). FIN No. 47 provides clarification with respect to the timing of liability recognition of legal obligations associated with the retirement of tangible long-lived assets when the timing and/or method of settlement of the obligation are conditional on a future event. FIN No. 47 is effective no later that the end of fiscal years ending after December 15, 2005. Retrospective application for interim financial information is permitted but is not required. There was no impact on our operating results or financial condition as a result of adopting this interpretation.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS No. 154). SFAS No. 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not contain specific transition provisions. When a pronouncement includes specific transition provisions, those provisions will continue to be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years

beginning after June 1, 2005. We do not expect the adoption of SFAS No. 154 to have a material impact on our consolidated financial statements.

In June 2005, the Emerging Issues Task Force issued Issue No. 05-6, "Determining the Amortization Period for Leasehold Improvements Purchased After Lease Inception or Acquired in a Business Combination" ("EITF No. 05-6"). EITF No. 05-6 states that leasehold improvements that are placed in service significantly after, and not contemplated at or near the beginning of the lease term, should be amortized over the shorter of the useful life of the assets or a term that includes the required lease periods and renewals that are deemed to be reasonably assured at the date the leasehold improvements are purchased. Leasehold improvements acquired in a business combination should be amortized over the shorter of the useful life of the assets or a term that includes required lease periods and renewals that are deemed to be reasonably assured at the date of acquisition. We are required to apply EITF No. 05-6 to leasehold improvements that are purchased or acquired in reporting periods beginning after June 29, 2005. There was no impact on our operating results or financial condition as a result of adopting EITF No. 05-6.

In February 2006, the FASB issued Statement No. 155, "Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140" (SFAS No. 155). SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The fair value election provided for in paragraph 4(c) of this Statement may also be applied upon adoption of this Statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this Statement. Earlier adoption is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued financial statements, including financial statements for any interim period for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our consolidated financial statements.

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 is 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 beginning on page F-1 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.

Item 9A. ***Controls and Procedures***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, the "Exchange Act") as of the end of the period covered by this annual report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, management has concluded that our internal control over financial reporting is effective as of December 31, 2005. Ernst & Young LLP, an independent registered public accounting firm that audited the Company's financial statements included in this annual report, has issued an attestation report on management's assessment of the Company's internal control over financial reporting. This report is included in our Consolidated Financial Statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control that occurred during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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," "Election of Directors — Board and Committee Matters," and "Section 16(a) Beneficial Reporting Compliance" in our Proxy Statement relating to our Annual Meeting of Stockholders scheduled for May 31, 2006 (the "Proxy Statement").

We have adopted a Code of Business Conduct and Ethics (the "code of ethics") that applies to all of our directors, officers and employees. The code of ethics is filed as an exhibit to this Report and we have posted the text of the code of ethics on our website which can be accessed at http://www.tripathimaging.com. Alternatively, interested parties may request, in writing, a copy of this Form 10-K, without charge. Such requests should be made to TriPath Imaging, Inc., Attn: Investor Relations, 780 Plantation Drive, Burlington, North Carolina 27215.

In addition, if we make any substantive amendments to the code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to any of our executive officers or directors, we will disclose the nature of such amendment or waiver on a Form 8-K.

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," and "Executive Compensation" in the Proxy Statement.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto under the captions "Share Ownership" and "Securities Authorized for Issuance Under Equity Compensation Plans" in the Proxy Statement.

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 "Certain Relationships and Related Transactions" in the Proxy Statement.

Item 14. *Principal Accountant Fees and Services*

The response to this item is incorporated herein by reference from the discussion responsive thereto under the caption "Information Concerning Our Auditor" in the Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(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(b) of this report.

(b) *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. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended June 30, 2004 (File No. 0-22885) and incorporated herein by reference.
10.2*	Amended and Restated 1997 Director Stock Option Plan. Filed as Exhibit 10.3 to the Company's Form 10-Q for the quarter ended June 30, 2004 (File No. 0-22885) 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 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.
10.9	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.
10.10	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.
10.11	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.

10.12 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.

10.13 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.

10.14 Sixth Amendment dated September 30, 2003 to Lease Agreement between TriPath Imaging, Inc. (as successor-in-interest to NeoPath, Inc.) and Teachers Insurance & Annuity Association dated October 1, 1994. Filed as Exhibit 10.14 to the Company's Form 10-K for the year ended December 31, 2003 (File No. 0-22885) and incorporated herein by reference.

10.15 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.

10.16† 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.

10.17 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.

10.18 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.

10.19 Lease Agreement dated as of July 1, 2002 by and between Banc of America Leasing & Capital, LLC and TriPath Imaging, Inc. Filed as Exhibit 10.24 to the Company's Form 10-K for the year ended December 31, 2002 (File No. 0-22885) and incorporated herein by reference.

10.20 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 as Exhibit 10.25 to the Company's Form 10-K for the year ended December 31, 2002 (File No. 0-22885) and incorporated herein by reference.

10.21 Fifth Loan Modification Agreement to the Loan and Security Agreement effective as of January 28, 2004 by and between Silicon Valley Bank and TriPath Imaging, Inc. Filed as Exhibit 10.21 to the Company's Form 10-K for the year ended December 31, 2003 (File No. 0-22885) and incorporated herein by reference.

10.22 Lease Agreement dated as of March 13, 2003 by and between General Electric Capital Corporation and TriPath Imaging, Inc. Filed as Exhibit 10.1 to our Form 10-Q for the quarter ended March 31, 2003 (File No. 0-22885) and incorporated herein by reference.

10.23 Addendum No. 1, dated September 1, 2003, to Sublease Agreement by and between NeoPath, Inc. and Antioch Bible Church dated as of August 31, 1999. Filed as Exhibit 10.23 to the Company's Form 10-K for the year ended December 31, 2003 (File No. 0-22885) and incorporated herein by reference.

10.24* Form of the Company's Incentive Stock Option Certificate under the Company's Amended and Restated 1996 Equity Incentive Plan for all its employees, including its executive officers. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended September 30, 2004 (File No. 0-22885) and incorporated herein by reference.

10.25* Form of the Company's Non-Statutory Stock Option Certificate under the Company's Amended and Restated 1996 Equity Incentive Plan for all its employees, including its executive officers, and its directors. Filed as Exhibit 10.2 to the Company's Form 10-Q for the quarter ended September 30, 2004 (File No. 0-22885) and incorporated herein by reference.

10.26* Form of the Company's Non-Statutory Stock Option Agreement under the Company's 1997 Director Stock Option Plan for its directors. Filed as Exhibit A to Appendix D to our Definitive Proxy Statement on Schedule 14A filed with the Commission on April 22, 2004 (File No. 0-22885) and incorporated herein by reference.

10.27*	Form of Director Option Agreement Amendment dated as of August 3, 2004 between the Company and Haywood D. Cochrane, Jr., Robert E. Curry, Ph.D., Richard A. Franco, R. Ph., Arthur King, Ph.D. and Robert L. Sullivan. Filed as Exhibit 10.4 to the Company's Form 10-Q for the quarter ended June 30, 1998 (File No. 0-22885) and incorporated herein by reference.
10.28*	Change of Control Agreement dated as of August 3, 2004 between the Company and Paul R. Sohmer, M.D. Filed as Exhibit 10.5 to the Company's Form 10-Q for the quarter ended September 30, 2004 (File No. 0-22885) and incorporated herein by reference.
10.29*	Form of Change of Control Agreement dated as of August 3, 2004 between the Company and Stephen P. Hall, Johnny D. Powers, Ph.D. and Ray W. Swanson, Jr. Filed as Exhibit 10.6 to the Company's Form 10-Q for the quarter ended September 30, 2004 (File No. 0-22885) and incorporated herein by reference.
10.30*	TriPath Imaging, Inc. 2006 Bonus Plan, adopted by the Compensation Committee of the Board of Directors on January 26, 2006. Filed herewith.
10.31*	Director Compensation at March 31, 2006. Filed herewith.
10.32*	Amendment to Lease dated August 1, 2004 between Carolina Hosiery Mills, Inc. and our Company. Filed as Exhibit 10.32 to the Company's Form 10-K for the year ended December 31, 2004 (File No. 0-22885) and incorporated herein by reference.
10.33*	TriPath Imaging, Inc. 2001 Employee Stock Purchase Plan. Filed as Appendix B to our Definitive Proxy Statement on Schedule 14A filed with the Commission on April 24, 2001 (File No. 0-22885) and incorporated herein by reference.
10.34*	Warrant Purchase Agreement between the Company and Quest Diagnostics Incorporated, dated as of May 5, 2004. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 2004 (File No. 0-22885) and incorporated herein by reference.
10.35*	Amendment No. 1 dated July 27, 2005 to the Amended and Restated 1996 Equity Incentive Plan. Filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended September 30, 2005 (File No. 0-22885) and incorporated herein by reference.
10.36*	Amendments dated May 24, 2005 and May 31, 2005 to Amended and Restated 1997 Director Stock Option Plan, filed as Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 2005 (File No. 0-22885) and incorporated herein by reference.
14.1	Code of Business Conduct and Ethics of the Company. Filed as Exhibit 14.1 to the Company's Form 10-K for the year ended December 31, 2003 (File No. 0-22885) and incorporated herein by reference.
21.1	List of all subsidiaries of the Company. Filed herewith.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm. Filed herewith.
31.1	Certification of Chief Executive Officer Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of Chief Financial Officer Pursuant to §240.13a-14 or §240.15d-14 of the Securities Exchange Act of 1934, as amended. Filed herewith.
32	Certification pursuant to 18 U.S.C. Section 1350. Filed herewith.
99.1	Factors Affecting Future Operating Results. Filed herewith.

* 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 February 28, 2006.

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 28th day of February, 2006.

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/ HAYWOOD D. COCHRANE, JR. Haywood D. Cochrane, Jr.	Director
/s/ ROBERT E. CURRY Robert E. Curry, Ph.D.	Director
/s/ RICHARD FRANCO Richard Franco	Director
/s/ ARTHUR T. KING Arthur T. King, Ph.D.	Director
/s/ GAIL F. LIEBERMAN Gail F. Lieberman	Director
/s/ ROBERT L. SULLIVAN Robert L. Sullivan	Director

TRIPATH IMAGING, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

TRIPATH IMAGING, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON THE FINANCIAL STATEMENTS

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, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005. 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 the standards of the Public Company Accounting Oversight Board (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, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of TriPath Imaging, Inc. internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 17, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 17, 2006

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

We have audited management's assessment, included in Item 9a of TriPath Imaging, Inc.'s Form 10-K filed with the Securities and Exchange Commission, that TriPath Imaging, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). TriPath Imaging, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that TriPath Imaging, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, TriPath Imaging, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of TriPath Imaging, Inc. and subsidiaries as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 of TriPath Imaging, Inc. and our report dated February 17, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, NC
February 17, 2006

TRIPATH IMAGING, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2005	December 31, 2004
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,457	$ 18,949
Accounts and notes receivable, net	15,647	12,976
Net investment in sales-type leases	828	667
Inventory, net	12,564	10,723
Other current assets	1,676	1,582
Total current assets	53,172	44,897
Customer use assets, net	8,044	7,688
Property and equipment, net	4,556	3,290
Other assets	2,362	2,734
Net investment in sales-type leases, net of current portion	1,807	1,043
Patents, less accumulated amortization of $4,433 and $3,752 at December 31, 2005 and 2004, respectively	5,111	5,792
Other intangible assets, less accumulated amortization of $1,427 and $1,229 at December 31, 2005 and 2004, respectively	1,916	2,090
Total assets	$ 76,968	$ 67,534
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,459	$ 3,668
Accrued expenses	5,323	3,750
Deferred revenue and customer deposits	1,106	1,551
Obligations under capital lease	23	—
Current portion of debt	—	19
Total current liabilities	10,911	8,988
Long-term portion of obligations under capital lease	98	—
Commitments and contingencies (Note 11)		
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; 38,324,632 and 38,127,501 shares issued and outstanding at December 31, 2005 and 2004, respectively	383	381
Additional paid-in capital	291,561	290,114
Deferred compensation	—	(11)
Accumulated deficit	(225,915)	(232,415)
Accumulated other comprehensive income	11	477
Treasury stock, at cost, 10,000 shares and 0 shares at December 31, 2005 and 2004, respectively	(81)	—
Total stockholders' equity	65,959	58,546
Total liabilities and stockholders' equity	$ 76,968	$ 67,534

See accompanying notes to consolidated financial statements.

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2005	2004	2003
	(In thousands, except per share amounts)		
Revenues	$85,961	$68,504	$53,764
Cost of revenues	26,035	21,230	18,377
Gross profit	59,926	47,274	35,387
Operating expenses:			
Research and development	12,352	11,280	8,861
Regulatory	3,403	3,882	5,434
Sales and marketing	24,440	18,640	18,324
General and administrative	13,552	13,138	11,687
	53,747	46,940	44,306
Operating income/(loss)	6,179	334	(8,919)
Interest income	605	289	413
Interest expense	(9)	(18)	(32)
Income/(loss) before income taxes	6,775	605	(8,538)
Income taxes	275	—	—
Net income/(loss)	$ 6,500	$ 605	$ (8,538)
Earnings/(loss) per common share			
Basic	$ 0.17	$ 0.02	$ (0.23)
Diluted	$ 0.17	$ 0.02	$ (0.23)

See accompanying notes to consolidated financial statements.

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Additional Paid-In Capital	Deferred Compensation	Accumulate Deficit	Accumulated Other Comprehensive Income/(Loss)	Treasury Stock	Total Stockholders' Equity
				(In thousands)			
Balance at January 1, 2003	$375	$283,396	$(78)	$(224,482)	$ (34)	—	$59,177
Exercise of options and warrants	3	1,232	—	—	—	—	1,235
Issuance of common stock under employee stock purchase plan	1	358	—	—	—	—	359
Re-pricing of stock options	—	49	—	—	—	—	49
Amortization of deferred compensation	—	—	26	—	—	—	26
Foreign currency translation	—	—	—	—	63	—	63
Net loss	—	—	—	(8,538)	—	—	(8,538)
Comprehensive loss	—	—	—	—	—	—	(8,475)
Balance at December 31, 2003	379	285,035	(52)	(233,020)	29	—	52,371
Exercise of options and warrants	2	967	—	—	—	—	969
Issuance of common stock under employee stock purchase plan	—	246	—	—	—	—	246
Issuance of warrants as consideration under incentive sales agreement	—	3,896	—	—	—	—	3,896
Adjustment to deferred compensation	—	(30)	30	—	—	—	—
Amortization of deferred compensation	—	—	11	—	—	—	11
Foreign currency translation	—	—	—	—	448	—	448
Net income	—	—	—	605	—	—	605
Comprehensive income	—	—	—	—	—	—	1,053
Balance at December 31, 2004	381	290,114	(11)	(232,415)	477	—	58,546
Exercise of options and warrants	2	713	—	—	—	—	715
Issuance of common stock under employee stock purchase plan	—	235	—	—	—	—	235
Issuance of warrants as consideration under incentive sales agreement	—	499	—	—	—	—	499
Amortization of deferred compensation	—	—	11	—	—	—	11
Purchase of Company stock	—	—	—	—	—	(81)	(81)
Foreign currency translation	—	—	—	—	(466)	—	(466)
Net income	—	—	—	6,500	—	—	6,500
Comprehensive income	—	—	—	—	—	—	6,034
Balance at December 31, 2005	$383	$291,561	$ —	$(225,915)	$ 11	(81)	$65,959

See accompanying notes to consolidated financial statements.

TRIPATH IMAGING, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2005	2004	2003
	(In thousands)		
OPERATING ACTIVITIES			
Net income/(loss)	$ 6,500	$ 605	$ (8,538)
Adjustments to reconcile net income/(loss) to net cash provided by (used in) operating activities:			
Depreciation	4,394	4,097	3,539
Amortization of intangible assets	879	830	817
Amortization of deferred compensation	11	11	26
Provision for doubtful accounts	50	3	180
Reserve for obsolete and slow-moving inventory	(308)	75	400
Non-cash equity compensation	—	—	49
Amortization of non-cash sales discount	1,278	519	—
Amortization of deferred research and development	—	(207)	(2,479)
Loss on disposal of fixed assets	—	24	13
Provision for income taxes	91	—	—
Changes in operating assets and liabilities:			
Accounts, notes and lease receivables	(2,994)	196	(4,363)
Inventory	(5,941)	(3,588)	(3,522)
Other current assets	(102)	702	(1,011)
Other long-term assets	(1,170)	(692)	443
Accounts payable and accrued expenses	2,309	(4,521)	3,927
Deferred revenue and customer deposits	(444)	46	395
Other current liabilities	—	—	(2,410)
Net cash provided by (used in) operating activities	4,553	(1,900)	(12,534)
INVESTING ACTIVITIES			
Purchases of property and equipment	(1,588)	(1,215)	(146)
Additions to other intangible assets	(24)	(319)	—
Other	—	(7)	196
Net cash (used in) provided by investing activities	(1,612)	(1,541)	50
FINANCING ACTIVITIES			
Issuance of common stock under employee stock purchase plan	235	246	359
Proceeds from exercise of stock options and warrants	715	969	1,235
Purchase of Company stock	(81)	—	—
Proceeds from debt	—	365	633
Payment of capital lease obligations	(14)		
Payments on debt and leases	(19)	(394)	(1,384)
Net cash provided by financing activities	836	1,186	843
Effect of exchange rate changes on cash	(269)	250	24
Net increase (decrease) in cash and cash equivalents	3,508	(2,005)	(11,617)
Cash and cash equivalents at beginning of year	18,949	20,954	32,571
Cash and cash equivalents at end of year	$22,457	$18,949	$ 20,954
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for interest	$ 9	$ 18	$ 32
Cash paid for income taxes	184	—	—
NON-CASH INVESTING AND FINANCING ACTIVITIES			
Issuance of warrants as consideration under incentive sales agreement	$ 499	$ 3,896	$ —
Capital lease obligations incurred	135	—	—

See accompanying notes to consolidated financial statements.

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 expertise 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 our efforts to develop new molecular diagnostic products for malignant melanoma and cancers of the cervix, breast, ovary, and prostate.

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 current products; and (2) TriPath Oncology, our wholly-owned subsidiary through which we manage the development and market introduction of molecular diagnostic products for cancer.

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

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 prior year amounts have been reclassified to conform to the 2005 presentation. These reclassifications had no effect on previously reported net income/(loss) 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 and other miscellaneous revenues.

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 is the predominant vehicle for international instrument sales. If, however, we sell an instrument directly to an international end user, we record the revenue upon installation and acceptance of the instrument, consistent with our treatment 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, revenue recognition occurs at the time of shipment of the reagent kits or on a monthly basis based on the actual or minimum usage. There is no capital equipment revenue recognized under these transactions.

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 respond to customer needs by offering both capital an operating lease alternatives. Under the capital lease alternative, revenue is recognized initially as an instrument sale with part of the lease payments being allocated to interest income, and service revenues, if applicable, over the lease term. Under operating leases, we do not recognize any revenue related to the instrument sale, but recognize revenue as rental income over the lease term.

Sales of consumable products are recorded on shipment. Billings and costs related to shipping products to customers are included in both revenues and cost of revenues, respectively.

Deferred Revenue

Deferred revenue principally consists of up-front cash receipts related to FocalPoint and PrepStain service and equipment contracts and the revenue portion subject to contingencies under capitalized leases. The deferred revenue subject to contingencies under capitalized leases will be recognized once those contingencies have been resolved. Revenue related to service and equipment contracts is recognized ratably over the life of the contract.

Cash and Cash Equivalents

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

Trade Receivables

Trade receivables are stated at outstanding principal less our allowance for doubtful accounts. We charge off uncollectible receivables against our allowance when the likelihood of collection is remote. We generally extend credit terms for 30 days domestically and for 90 days internationally, but may, depending on the circumstances, extend credit terms for longer periods of time. Amounts outstanding beyond our credit terms are considered past due. We generally grant credit without requiring collateral. We maintain an allowance for doubtful accounts, which is determined based on various factors, including our accounts receivable aging, customer credit-worthiness, historical bad debts and current economic trends.

Notes Receivable

Notes receivable are stated at outstanding principal less unearned discounts for interest receivable and our allowance for doubtful accounts. Our policy for uncollectible notes receivable and our accounting treatment of the allowance for doubtful accounts is the same as that noted under *Trade Receivables* above. At December 31, 2005 and 2004, unearned discounts for interest receivable amounted to $102 and $0, respectively.

Net investment in sales-type leases

In connection with our fee-per-use equipment usage agreements with customers, we allow customers to use the instruments for more than 75% over the estimated useful life of the asset, generally with terms between 42 and 60 months. As a result, these arrangements are treated as sales-type leases, in accordance with accounting principles generally accepted in the United States of America. At December 31, 2005 and 2004, unearned discounts for interest receivable amounted to $326 and $235, respectively.

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, movement and other factors.

Customer-Use Assets

PrepStain and FocalPoint systems manufactured for fee-per-use or operating lease placements are carried in inventory until the systems are shipped, at which time they are moved to customer-use assets (non-current assets). Net movements of $3,654, $3,790, and $2,381 occurred between customer-use assets and inventory during 2005, 2004, and 2003, respectively. Customer-use assets are depreciated to the estimated residual value on a straight-line basis over their estimated useful life, which ranges from four to seven years. Depreciation expense of customer-use assets amounted to $3,298, $2,715, and $2,103 during 2005, 2004, and 2003, respectively.

Prior to October 1, 2005, we estimated a $0 salvage value to our FocalPoint systems being used as customer-use assets. However, based upon periodic evaluation of these units, we increased the salvage value on our FocalPoint systems from $0 to $60 per instrument. We believe the revised amount reflects the historical experience and more appropriately reflects the salvage value of these assets. This change in accounting estimate decreased 2005 depreciation expense by approximately $170.

Property and Equipment

Property and equipment is stated at cost and is depreciated to the estimated residual values on a straight-line basis over the estimated useful lives (typically three to seven years) of the individual assets. Leased property under capital leases, included in property and equipment, is stated at cost and is amortized on a similar basis. Leasehold improvements are amortized over the lesser of the estimated useful lives or the remaining term of the lease.

Depreciation expense of property and equipment, which also includes amortization of assets recorded under capital leases, amounted to $1,096, $1,382, and $1,436 during 2005, 2004, and 2003, respectively. Net movements of $656, ($62) and $817 occurred between property and equipment and inventory during 2005, 2004 and 2003, respectively.

Patents

Patents consist of patents and core technology acquired from Neuromedical Systems, Inc. Such assets are amortized using the straight-line method over estimated useful lives ranging from 14 to 20 years. Included in operations in 2005, 2004 and 2003, respectively, is $681, $667 and $667 of amortization expense attributable to patents. Annual amortization expense of $681 is expected to continue until the patents are fully amortized.

Other Intangible Assets

Other intangible assets consist of acquired rights to certain intellectual property surrounding our pathology workstation products, our location-guided screening technology and our molecular diagnostic products. Such assets are amortized using the straight-line method over estimated useful lives ranging from 10 to 20 years. Amortization expense of other intangible assets amounted to $198, $163, and $150 during 2005, 2004, and 2003, respectively. An annual amortization rate of $206 is anticipated from 2006 onwards based on our other intangible assets in existence at December 31, 2005.

Impairment of Long-Lived Assets and Recoverability of Intangibles

We account for impairments of long-lived and intangible assets subject to amortization using SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets.* SFAS No. 144 requires that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted cash flows and (2) subsequently measure an impairment loss as the difference between the carrying amount and fair value of the asset.

Product Warranty Obligation

We record a liability for product warranty obligations at the time of sale based upon historical warranty experience. The term of the warranty is generally twelve months. We also record an additional liability for specific

warranty matters when they become known and are reasonably estimable. We typically do not accept product returns. The product warranty obligations are recorded as a component of accrued expenses.

A summary of the product warranty obligation reserve activity is as follows:

	December 31,		
	2005	2004	2003
Balance, beginning of year	$(159)	$(387)	$(440)
Accruals	(222)	(175)	(311)
Settlements made	109	208	334
Warranties expired/adjustments	139	195	30
Balance, end of year	$(133)	$(159)	$(387)

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 and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded against the deferred tax asset when it is more likely than not that some or all of the deferred tax asset will not be realized. We have established valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2005 and 2004, 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 fair value, we record deferred compensation expense for the difference between the exercise price of the shares and the fair value. Any resulting deferred compensation expense is amortized ratably over the vesting period of the individual options.

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 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"), which 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).

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 and 148, with respect to our Equity Incentive Plan and our Employee Stock Purchase Plan (see Note 7), our pro forma net loss and loss per share would have been as follows:

	Year-Ended December 31,		
	2005	2004	2003
Net income/(loss), as reported	$ 6,500	$ 605	$ (8,538)
Stock-based compensation included in reported net income/(loss)	11	11	26
Stock-based compensation expense under fair value based method for all plans	(10,469)	(5,145)	(3,536)
Pro forma net loss	$ (3,958)	$(4,529)	$(12,048)
Earnings/(loss) per common share			
Basic:			
As reported	$ 0.17	$ 0.02	$ (0.23)
Pro forma	$ (0.10)	$ (0.12)	$ (0.32)
Diluted:			
As reported	$ 0.17	$ 0.02	$ (0.23)
Pro forma	$ (0.10)	$ (0.12)	$ (0.32)

See also *Recently Issued Accounting Standards* below.

Earnings/(Loss) Per Common Share

We follow the provisions of SFAS No. 128, "Earnings Per Share", which requires us to present basic and diluted earnings/(loss) per share. Basic earnings/(loss) per share information is calculated by dividing the net income/(loss) by the weighted-average number of shares of common stock outstanding during all periods presented. Diluted earnings per share is calculated by dividing net income/(loss) by the weighted-average number of shares of common stock outstanding after giving effect to all potentially dilutive shares of common stock, as if they had been issued at the beginning of the period presented. Potentially dilutive shares of common stock result from our outstanding stock options and warrants. Certain potential shares, attributable to certain stock options and warrants, were excluded from diluted earnings per share because their impact was antidilutive. The calculation of diluted loss per share for 2003 excludes all potential shares because their effect would be antidilutive (see Note 7).

Advertising Expense

The cost of advertising is expensed as incurred. Advertising and marketing expense, including expenses related to participation in trade shows, amounted to $1,645, $1,354, and $793 during 2005, 2004, and 2003, 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 has been reported in other comprehensive income/(loss). The effect on the consolidated statements of operations of transaction gains and losses is insignificant for all years presented.

Comprehensive Income/(Loss)

We follow SFAS No. 130, "Reporting Comprehensive Income" which requires that we display an amount representing comprehensive income/(loss), which represents total net income/(loss) and all other non owner changes in equity including foreign currency translation adjustments, net of tax, 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 and Financial Instruments

Our principal financial instruments subject to potential concentration of credit risk are cash and cash equivalents, trade receivables, investments in sales-type leases and notes receivable, and accounts payable and accrued expenses. We invest our funds in highly rated institutions and believe that the financial risks associated with cash and cash equivalents are minimal. The fair values of our financial instruments approximate their carrying values due to their relatively short maturity and our discounting of unearned interest receivable. We limit our exposure in any individual receivable and financial instrument. We provide an allowance for doubtful accounts equal to the estimated losses to be incurred in the collection of trade receivables, investments in sales-type leases and notes receivable and discount our notes receivable for unearned interest receivable.

Recently Issued Accounting Standards

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — an Amendment of ARB No. 43, Chapter 4" ("SFAS No. 151") to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "... under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges... .". SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier adoption permitted. The provisions of SFAS No. 151 shall be applied prospectively. We adopted this Standard as of January 1, 2006 and the adoption did not have a material impact on our consolidated financial statements.

In December 2004, the FASB issued Statement No. 153, "Exchanges of Nonmonetary Assets — an amendment of APB Opinion No. 29" ("SFAS No. 153"). SFAS No. 153 addresses the measurement of exchanges of nonmonetary assets. The guidance in APB Opinion No. 29, "Accounting for Nonmonetary Transactions", is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. SFAS No. 153 amends APB Opinion No. 29 to eliminate the exception of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for financial statements for fiscal years beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges incurred during fiscal years beginning after the date this Statement is issued. We do not expect the adoption of SFAS No. 153 to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Share Based Payment" ("SFAS No. 123(R)"). SFAS No. 123(R) is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation," and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123(R) eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements using a fair value-based method. SFAS No. 123(R) was to be effective as of the beginning of the first interim period that began after June 15, 2005. In April of 2005, the U.S. Securities and

Exchange Commission ("SEC") announced that it would delay the effective date for financial statement compliance with SFAS No. 123(R) until the first annual reporting period of the registrant's first fiscal year beginning after June 15, 2005. We adopted this Standard as of January 1, 2006 and will use the modified prospective application transition method. Our current estimate for the non-cash impact of implementing FAS 123(R) on existing stock-based compensation instruments is less than $0.01 per share for full year 2006. However, if we issue annual grants of stock-based compensation instruments during 2006, as we typically do around the time of our annual shareholders' meeting in May, there will be additional impact on our earnings per share. Our current estimate of the total stock-based compensation expense in 2006, if stock-based compensation is granted, is an impact to earnings per share of between $0.01 and $0.02 per share, principally during the second half of 2006.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations — an interpretation of SFAS No. 143" ("FIN No. 47"). FIN No. 47 provides clarification with respect to the timing of liability recognition of legal obligations associated with the retirement of tangible long-lived assets when the timing and/or method of settlement of the obligation are conditional on a future event. FIN No. 47 is effective no later that the end of fiscal years ending after December 15, 2005. Retrospective application for interim financial information is permitted but is not required. There was no impact on our consolidated financial statements as a result of adopting this interpretation.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS No. 154). SFAS No. 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not contain specific transition provisions. When a pronouncement includes specific transition provisions, those provisions will continue to be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years beginning after June 1, 2005. We do not expect the adoption of SFAS No. 154 to have a material impact on our consolidated financial statements.

In June 2005, the Emerging Issues Task Force issued Issue No. 05-6, "Determining the Amortization Period for Leasehold Improvements Purchased After Lease Inception or Acquired in a Business Combination" ("EITF No. 05-6"). EITF No. 05-6 states that leasehold improvements that are placed in service significantly after, and not contemplated at or near the beginning of the lease term, should be amortized over the shorter of the useful life of the assets or a term that includes the required lease periods and renewals that are deemed to be reasonably assured at the date the leasehold improvements are purchased. Leasehold improvements acquired in a business combination should be amortized over the shorter of the useful life of the assets or a term that includes required lease periods and renewals that are deemed to be reasonably assured at the date of acquisition. We are required to apply EITF No. 05-6 to leasehold improvements that are purchased or acquired in reporting periods beginning after June 29, 2005. There was no impact on our consolidated financial statements as a result of adopting EITF No. 05-6.

In February 2006, the FASB issued Statement No. 155, "Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140" (SFAS No. 155). SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. The fair value election provided for in paragraph 4(c)

of this Statement may also be applied upon adoption of this Statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this Statement. Earlier adoption is permitted as of the beginning of an entity's fiscal year, provided the entity has not yet issued financial statements, including financial statements for any interim period for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our consolidated financial statements.

3. Financial Statement Information

Select detailed financial statement information is as follows:

	December 31, 2005	December 31, 2004
Accounts and notes receivable		
Trade accounts receivable	$ 16,081	$ 13,477
Current portion of notes receivable	591	584
Other accounts receivable	65	177
	16,737	14,238
Allowance for doubtful accounts	(1,090)	(1,262)
	15,647	12,976
Inventory		
Stage of production:		
Raw materials	$ 10,052	$ 9,067
Work-in-process	861	1,747
Finished goods	4,355	3,014
	15,268	13,828
Reserves for obsolete and slow moving inventory	(2,704)	(3,105)
	$ 12,564	$ 10,723
Categories:		
Instruments	$ 13,197	$ 12,293
Reagents and consumables	2,071	1,535
	15,268	13,828
Reserves for obsolete and slow moving inventory	(2,704)	(3,105)
	$ 12,564	$ 10,723
Other current assets		
Current portion of deferred sales discount	$ 779	$ 779
Other assets	897	803
	$ 1,676	$ 1,582
Customer-use assets		
Customer-use systems	$ 17,400	$ 14,696
Accumulated depreciation	(9,356)	(7,008)
	$ 8,044	$ 7,688

	December 31,	
	2005	2004
Property and equipment		
Machinery and equipment	$ 4,574	$ 4,051
Demonstration equipment	4,172	3,490
Furniture, fixtures and improvements	1,940	1,696
Leasehold improvements	1,589	1,362
Vehicles	10	10
Computer equipment and software	5,407	5,257
Machinery and equipment under capital lease	135	—
Total property and equipment	17,827	15,866
Accumulated depreciation	(13,271)	(12,576)
	$ 4,556	$ 3,290
Other assets		
Notes receivable, net of current portion	$ 750	110
Deferred sales discount, net of current portion	1,819	2,597
Deposits	27	27
Allowance for doubtful accounts	(234)	—
	$ 2,362	$ 2,734
Accrued expenses		
Accrued payroll and related benefits	$ 3,689	$ 2,488
Accrued taxes	968	681
Accrued warranty costs	133	159
Other accrued expenses	533	422
	$ 5,323	$ 3,750

4. Allowance for Doubtful Accounts

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

	December 31,		
	2005	2004	2003
Balance, beginning of year	$1,262	$ 2,277	$ 3,554
Amounts charged to expense	50	3	180
Amounts charged to allowance	(4)	(1,018)	(1,457)
Recoveries	16	—	—
Balance, end of year	$1,324	$ 1,262	$ 2,277

As noted above, $1,090 of the December 31, 2005 allowance for doubtful accounts balance is allocated to trade receivables and the current portion of notes receivable, while the remaining $234 is allocated to the long-term portion of notes receivable.

5. Long-Term Obligations and Commitments

Working Capital Facility

In January 2005, we renewed our $7,500 working capital facility with Silicon Valley Bank. We also extended the term of the line of credit to 15 months with an expiration date of April 27, 2006. The entire amount of the line is available as long as certain financial covenants are met. If these covenants are not met, the available balance is limited to an amount equal to 80% of eligible accounts receivable. At December 31, 2005, we were entitled to borrow the full amount of the line. The renewed line offers either a prime-based (prime plus 0.25%) or LIBOR-based (LIBOR plus 2.0%) pricing option for advances made under it 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, 2005. At December 31, 2004, maturities of other outstanding short-term debt raised to fund working capital were $19, all of which were repaid in the first quarter of 2005.

Leases and Lease Lines of Credit

During April 2003, we obtained a $2,500 lease line of credit from General Electric Capital Corporation ("GE Capital"). Individual operating lease schedules under this lease line carry three-year terms. Financing charges are based on the fixed basic term lease rate factor. The interest rates on the various schedules which are incorporated into the lease payments under this lease line, which are incorporated into the operating lease payments, range from 2.85% to 3.45%. The lease line is being used as an alternative source of capital to secure operating leases for assets, primarily equipment. In March 2004, this line was renewed for $2,000 (in addition to amounts for assets already leased under the line). Terms of the new line are substantially the same as the expiring line. The primary difference is that lease terms under the new line range from 30 to 36 months. As of December 31, 2005 and 2004, respectively, assets with an original cost of $1,917 and $1,707 were leased under our lease lines with GE Capital. Future minimum lease payments under this lease line are $1,023 as of December 31, 2005.

During August 2002, we obtained a $1,500 lease line of credit from Bank of America. Bank of America assigned the leases under this line to GE Capital in 2004. Amounts used under this lease line are secured by a letter of credit against our line of credit with Silicon Valley Bank discussed above. Assets leased under this lease line carry three-year lease terms. Financing charges are based on three-year constant Treasury Maturities. The interest rates on the various schedules under this lease line, which are incorporated into the operating lease payments, range from 2.75% to 2.90%. The lease line was used as an alternative source of capital to secure operating leases for assets, primarily equipment. As of December 31, 2005 and 2004 assets with an original cost of $1,286 were leased under

this lease line. Future minimum lease payments under this lease line are $345 as of December 31, 2005. As the lease line has expired, no further assets will be leased under this line of credit.

We also lease our office and manufacturing facilities and certain other equipment under operating and capital leases, with various renewal options, expiring at various times through 2018. Certain leases for manufacturing facilities are subject to escalating payments throughout the remaining lease term. These escalations are recorded as a component of rent expense on a straight-line basis over the remaining lease term.

At December 31, 2005, future minimum lease payments under operating and capital leases are as follows:

2006	$ 2,252
2007	1,535
2008	1,022
2009	827
2010	672
Thereafter	5,641
	$11,949

Future minimum lease payments under capital leases amount to $28 in 2006 through 2009 and $23 in 2010.

Rent expense under operating and capital leases amounted to $2,504, $2,066 and $2,280 during 2005, 2004 and 2003, respectively.

The following lists the components of the net investment in sales-type leases:

	2005	2004
Total minimum rentals	$3,188	$2,206
Less amounts representing estimated maintenance costs included in total minimum rentals	(532)	(261)
Net minimum lease payments	2,656	1,945
Estimated residual values of leased property (unguaranteed)	305	—
Less unearned income	(326)	(235)
Net investment in sales-type leases	$2,635	$1,710

Minimum lease payments do not include contingent rentals, which may be received under certain leases of capital equipment on the basis of usage in excess of stipulated minimums. Contingent rentals amounted to $17 and $2 for 2005 and 2004, respectively.

At December 31, 2005, future minimum lease payments under sales-type leases are as follows:

2006	$1,163
2007	1,052
2008	650
2009	240
2010	83
Thereafter	—
	$3,188

Other Liabilities and Commitments

On July 31, 2001, we entered into a series of agreements with Becton, Dickinson and Company ("BD") to develop and commercialize tests for malignant melanoma and cancers of the cervix, breast, ovary and prostate using genomic and proteomic markers identified at 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 was amortized against such expenses over thirty months on a straight-line basis. During 2004 we recorded $207 of amortization against R&D expenses. This deferred R&D funding was fully amortized as of January 31, 2004.

During 2001 we entered into a contract with a vendor in Switzerland to purchase a minimum of 300 and up to 525 base units for our PrepStain instrument. Under the terms of the original contract we committed to purchase at least 300 complete units by December 31, 2004, and to the extent that we purchased less than 525 complete units, we would have been obligated to purchase component parts for the balance by the end of 2005. In late 2004 and early 2005 we negotiated a favorable conclusion to this contractual agreement with the supplier and committed to purchase a further 25 base units in 2005. Having purchased the required 25 base units during 2005, we have no further commitment under this contract.

6. Income taxes

The domestic and foreign components of income/(loss) before income taxes were as follows:

	2005	2004	2003
Domestic	$5,832	$1,084	$(8,721)
Foreign	943	(479)	183
Total	$6,775	$ 605	$(8,538)

Income taxes consist of the following:

	2005	2004	2003
Current provision:			
U.S. Federal	$141	$—	$—
State	69	—	—
Foreign	65	—	—
Total current	$275	$—	$—
Total deferred	$ —	$—	$—
Total income taxes	$275	$—	$—

At December 31, 2005, we had net operating loss carryforwards of approximately $211,928 for federal income tax purposes and approximately $91,550 for state income tax purposes. We also had approximately $2,429 in research and development credit carryforwards and $144 alternative minimum tax credit carryforwards. The federal and state net operating loss carryforwards have expiration periods that begin in 2007 and 2006, respectively, and end in 2024. The research and development credit carryforwards have expiration periods that begin in 2017 and end in 2025. The alternative minimum tax credit carryforward has no expiration date. Approximately $6,990 of the net tax loss carryforwards is attributed to deductions for stock options, the tax effect of which is credited to equity when recognized.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions, ownership changes with respect to a 1995 stock issuance and our 1999 merger with NeoPath, Inc. have

resulted in the imposition of substantial annual limitations on our use of net operating losses and credit carryforwards attributable to periods before the changes.

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,	
	2005	2004
Deferred tax assets:		
Federal and state net tax loss carryforwards	$ 76,941	$ 83,340
Research and development credits	2,429	4,171
Accrued vacation	133	149
Accrued warranty costs	51	60
Allowance for doubtful accounts	503	480
Charitable contribution carryforwards	8	22
Non-cash sales discounts	683	197
Intangible assets, net of amortization	1,718	1,902
Inventory	1,551	1,694
AMT carryforwards	144	—
Other	192	161
Total gross deferred tax assets	84,353	92,176
Valuation allowance	(84,291)	(91,968)
Net deferred tax asset	62	208
Deferred tax liabilities:		
Property and equipment	(62)	(208)
Net deferred tax asset	$ —	$ —

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. The change in valuation allowance was approximately a $7,677 reduction between 2004 and 2005.

A reconciliation of the federal statutory rate to our effective income tax rate is as follows:

	2005	2004	2003
Income tax provision at federal statutory rate	35.0%	35.0%	35.0%
State income tax, net	0.6	3.0	—
Foreign income or loss at federal statutory rate	(4.9)	27.7	0.8
Foreign taxes	1.0	—	—
Loss and credit carryforwards	81.6	(1,144.6)	1.0
Permanent items and other	4.1	52.3	18.0
Change in valuation allowance	(113.3)	1,026.6	(54.8)
Effective tax rate	4.1%	—	—

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 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, 2005 there were no shares of Preferred Stock outstanding.

Common Stock

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 was 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, in July 2001 we entered into a research license for our evaluation of certain patents in the area of colon cancer with Millennium. 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. In May 2003, we decided not to exercise our rights to the colon cancer license and not to develop technology related to colon cancer through our collaboration with BD.

Earnings/(Loss) Per Share

The following table represents a reconciliation of the weighted average shares used in the calculation of basic and diluted earnings/(loss) per share:

	2005	2004	2003
Basic	38,218,333	38,005,626	37,626,268
Assumed conversion of:			
Stock options	997,682	1,084,074	—
Warrants	53,754	61,058	—
Diluted	39,269,769	39,150,758	37,626,268

The following table summarizes the potential common shares not included in the computation of diluted earnings /(loss) per share because their impact would have been antidilutive:

	2005	2004	2003
Stock options	3,313,189	1,931,148	3,827,347
Warrants	1,500,000	800,000	223,253
	4,813,189	2,731,148	4,050,600

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.

In November 1996, we adopted the 1996 Equity Plan. Pursuant to the 1996 Equity Plan, our employees, employees of our subsidiaries, directors and consultants may receive options to purchase common stock and other

common stock awards. The 1996 Equity Plan is administered by the Compensation Committee. A maximum of 7,996,325 shares have been authorized to cover grants and awards under the 1996 Equity Plan.

In June 1997, we adopted the 1997 Director Plan. Pursuant to the 1997 Director Plan, eligible directors may receive options to purchase common stock. Additionally, each time an eligible director is elected or re-elected to the Board of Directors, the eligible director is automatically granted an option to purchase 30,000 shares of our common stock. The 1997 Director Plan is administered by the Board of Directors. A maximum of 450,000 shares have been authorized to cover grants and awards under the 1997 Director Plan.

We also have two plans from our merger with NeoPath, Inc. in 1999, the NeoPath 1989 Stock Option Plan and NeoPath 1999 Plan. No further shares of common stock are available for grant or award under these plans, which have balances of unexercised shares of 97,453 and 45,741, respectively as of December 31, 2005.

For years covered by this report, stock options are the only instrument granted or issued under these plans. For directors, stock options vested ratably over 36 months. On May 31, 2005, the Board of Directors amended the vesting schedule under the Plan so new options granted under the Plan now are 50% vested on December 31 of the year in which the grant is made and then vest ratably over the next three years.

Stock options granted to employees vest ratably every 12 months and are fully vested after 48 months.

The exercise price of options granted, as determined by the Compensation Committee or Board of Directors, approximates fair market value of our common stock at the time of the grant.

On May 31, 2005 and December 30, 2005, respectively, we accelerated the vesting of stock options that were both unvested and "out-of-the-money" and held by current employees, officers and directors with exercise prices greater than or equal to $8.89, which was $0.25 higher than the closing sales price of our common stock on the Nasdaq National Market on May 27, 2005, and $7.00, which was $0.97 higher than the closing sales price of our common stock on the Nasdaq National Market on December 29, 2005. The primary purpose of the vesting acceleration was to enable us to minimize future compensation expense associated with the accelerated options upon our planned adoption of SFAS Statement No. 123(R).

A summary of activity under the Plans is as follows:

	Options Outstanding	
	Number of Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2002	3,766,983	$ 6.74
Options granted	594,400	4.04
Options exercised	(233,493)	5.34
Options canceled/expired	(300,543)	7.19
Outstanding at December 31, 2003	3,827,347	$ 6.37
Options granted	1,315,849	9.02
Options exercised	(197,197)	4.95
Options canceled/expired	(372,361)	10.10
Outstanding at December 31, 2004	4,573,638	$ 6.89
Options granted	1,641,648	8.60
Options exercised	(165,867)	4.27
Options canceled/expired	(236,257)	8.84
Outstanding at December 31, 2005	5,813,162	$ 7.37

Price Range	Options Outstanding: Number Outstanding at December 31, 2005	Options Outstanding: Weighted-Average Remaining Contractual Life (Years)	Options Outstanding: Weighted-Average Exercise Price	Options Exercisable: Number Exercisable at December 31, 2005	Options Exercisable: Weighted-Average Exercise Price
$ 0.20 - $ 0.21	65,556	0.9	$ 0.20	65,556	$ 0.20
1.99 - 2.81	340,300	7.1	2.48	236,297	2.47
3.05 - 4.57	582,802	4.9	4.25	543,265	4.25
4.67 - 7.00	1,378,931	4.8	5.40	1,347,384	5.37
7.01 - 10.00	2,830,215	8.7	8.77	2,827,221	8.77
10.94 - 10.94	523,000	5.1	10.94	523,000	10.94
16.45 - 16.45	92,358	2.2	16.45	92,358	16.45
$ 0.20 - $16.45	5,813,162	6.8	$ 7.37	5,635,081	$ 7.48

Employee Stock Purchase Plan

In 2002, we introduced our TriPath Imaging, Inc. Employee Stock Purchase Plan with 1,000,000 shares of common stock for authorized issuance. The plan qualifies as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code and 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:

	2005	2004	2003
June	14,088	20,964	50,631
December	25,561	13,235	22,940
	39,649	34,199	73,571

SFAS 123

We have adopted the disclosure-only provisions of SFAS 123 and presented the relevant disclosures in Note 2. 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,		
	2005	2004	2003
Risk-free interest rate	3.75%	3.23%	2.45%
Expected dividend yield	0.00%	0.00%	0.00%
Expected lives	48 months	48 months	48 months
Expected volatility	0.53	0.85	0.93
Weighted-average fair value of grants	$8.60	$9.02	$4.04

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. These warrants were exercised during November 2003 using a net issuance provision resulting in the issuance of 12,997 shares.

On February 8, 2000, we closed a $7,000 subordinated term loan with a syndicate of lenders to finance operations. 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. In January 2004, 100,583 of these warrants were exercised using the net issuance provision contained in such warrants resulting in the issuance of 41,677 shares. The remaining 122,670 warrants outstanding have a weighted average exercise price of $4.28 and expire in January 2007.

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. The warrants were not exercised and expired in November 2003 pursuant to their terms.

In May 2004, we entered into a multi-year agreement with Quest Diagnostics Incorporated ("Quest Diagnostics") pursuant to the terms of which Quest Diagnostics uses our SurePath and PrepStain products. In connection with the agreement, we issued Quest Diagnostics warrants with respect to an aggregate of 4,000,000 shares of our common stock, which are described in the following table:

Warrant	Shares Subject to Warrants	Exercise Price (per share)	Warrant Expiration Date	Vesting Status
First Tranche....	800,000	$ 9.25	May 2007	Currently Exercisable
Second Tranche..	200,000	$10.18	May 2007	Currently Exercisable
Third Tranche...	500,000	$10.64	May 2007	Currently Exercisable
Fourth Tranche ..	1,000,000	$11.56	May 2008	Exercisable Upon Achievement of Sales Milestone
Fifth Tranche ...	1,500,000	$12.03	May 2008	Exercisable Upon Achievement of Sales Milestone

The warrants permit exercise on a net issuance basis and are subject to a lock-up provision, which prohibits sales and other transfers of the underlying shares for a two-year period ending in May 2006, at which point 50% of the shares underlying warrants then exercisable may be transferred, and subjects the remaining underlying shares to an additional one year lock-up.

— First Tranche Warrants

The First Tranche warrants were exercisable upon the commencement of the agreement with Quest Diagnostics. Using the guidance in the FASB's Emerging Issues Task Force Release 01-9, *"Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products),"* these warrants were valued (on the basis of the fair value of the warrants at the date of grant) using a Black-Scholes pricing model upon issuance at $3,896, which represented a deferred sales discount. The value of the warrants was recorded as additional paid-in capital and the resulting deferred sales discount is being amortized on a straight-line basis against revenues over the five-year term of the agreement. Non-cash sales discounts of $779 and $519 were recorded in 2005 and 2004, respectively, in connection with the First Tranche warrants.

— Sales-Based Milestone Warrants

Our agreement with Quest Diagnostics links the exercisability of the Second Tranche, Third Tranche, Fourth Tranche and Fifth Tranche warrants to the achievement of sales-based milestones, which have been met for the Second Tranche and Third Tranche. These milestones are based on the volume of SurePath tests purchased by Quest Diagnostics within specified time periods. When it becomes probable that a tranche of warrants will become exercisable upon the achievement of the applicable sales-based milestone, we accrue the resulting sales discounts

over the related number of tests in the six-month period for which the milestone is achieved as further described below.

— *Second and Third Tranche Warrants*

During 2005, the Second and Third Tranche warrants vested upon the achievement of the sales-based milestone applicable to those warrants. Using the guidance in the FASB's Emerging Issues Task Force Release 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"* ("EITF 96-18"), the 200,000 Second Tranche warrants were valued at $224 using a Black-Scholes pricing model, which was recorded as a reduction of revenues with a corresponding credit to additional paid-in capital. Additionally, the 500,000 Third Tranche warrants were valued at $275 using a Black-Scholes pricing model, which was recorded as a reduction of revenues with a corresponding credit to additional paid-in capital.

When and if it becomes apparent that any of the remaining tranches of currently unexercisable warrants held by Quest may vest upon the achievement of the applicable sales-based milestone, we will accrue the resulting deferred sales discounts over the related number of tests in the six-month period for which the warrants were earned.

— *Summary*

During 2005 and 2004, respectively, we recorded $1,278 and $519, respectively, of amortization of deferred and accrued sales discounts as a reduction of revenues. Included in 'other current assets' and 'other assets' at December 31, 2005 and 2004 are the unamortized balances of $779 and $779 and $1,819 and $2,597, respectively.

As of December 31, 2005, there were a total of 1,622,670 currently exercisable common stock warrants outstanding with a weighted-average exercise price of $7.62. These warrants expire in January and May 2007.

Common Stock Reserved for Future Issuance

At December 31, 2005, we have reserved authorized shares of common stock for future issuance as follows:

	December 31, 2005
Outstanding stock options	5,813,162
Possible future issuance under equity incentive plans	436,204
Possible future issuance under Employee Stock Purchase Plan	777,282
Common stock warrants currently exercisable	1,622,670
Common stock warrants exercisable upon achievement of sales-based milestone	2,500,000
Total shares reserved	11,149,318

Deferred Compensation

In accordance with APB 25, for stock options and restricted stock grants granted at exercise prices below fair value, we record deferred compensation expense for the difference between the exercise price of the shares and the fair value. The amounts are amortized to compensation expense over the vesting period of the individual options, generally 48 months. Amortization of deferred compensation amounted to $11, $11 and $26 during 2005, 2004 and 2003, respectively. We adjusted the deferred compensation amount by $30 in 2004 to reflect the cancellation of options granted to terminated employees.

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 income 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 or seek to develop different products and services. The reportable segments are each managed separately because they do or seek to develop and commercialize distinct products. The segments operate as separate entities.

Results by Segment

The results, by segment, for 2005, 2004 and 2003 follow:

	2005		
	Commercial Operations	TriPath Oncology	Total
Revenues	$84,157	$ 1,804	$85,961
Cost of revenues	24,981	1,054	26,035
Gross profit	59,176	750	59,926
Operating expenses:			
Research and development	2,004	10,348	12,352
Regulatory	2,450	953	3,403
Sales and marketing	23,926	514	24,440
General and administrative	8,721	4,831	13,552
	37,101	16,646	53,747
Operating income/(loss)	$22,075	$(15,896)	$ 6,179

	2004		
	Commercial Operations	TriPath Oncology	Total
Revenues	$67,862	$ 642	$68,504
Cost of revenues	21,072	158	21,230
Gross profit	46,790	484	47,274
Operating expenses:			
Research and development	2,005	9,275	11,280
Regulatory	3,263	619	3,882
Sales and marketing	18,126	514	18,640
General and administrative	8,652	4,486	13,138
	32,046	14,894	46,940
Operating income/(loss)	$14,744	$(14,410)	$ 334

	2003		
	Commercial Operations	TriPath Oncology	Total
Revenues	$53,631	$ 133	$53,764
Cost of revenues	18,361	16	18,377
Gross profit	35,270	117	35,387
Operating expenses:			
Research and development	2,319	6,542	8,861
Regulatory	4,763	671	5,434
Sales and marketing	17,318	1,006	18,324
General and administrative	7,264	4,423	11,687
	31,664	12,642	44,306
Operating income/(loss)	$ 3,606	$(12,525)	$ (8,919)

All sales reflected in the tables above were from external customers. Inter-segment revenues of $1,054, $158 and $16 were eliminated on consolidation for 2005, 2004 and 2003, respectively. Sales to external customers for the years ended December 31, 2005, 2004 and 2003, include the following:

	2005	2004	2003
Instruments			
Commercial Operations	$ 6,929	$ 7,029	$ 7,528
TriPath Oncology	1,157	130	—
Total instruments	$ 8,086	$ 7,159	$ 7,528
Reagents			
Commercial Operations	$68,238	$52,683	$39,013
TriPath Oncology	33	—	—
Total reagents	$68,271	$52,683	$39,013
Fee-per-use and other			
Commercial Operations	$ 8,990	$ 8,150	$ 7,090
TriPath Oncology	614	512	133
Total fee-per-use and other	$ 9,604	$ 8,662	$ 7,223
Total revenues			
Commercial Operations	$84,157	$67,862	$53,631
TriPath Oncology	1,804	642	133
Total consolidated revenues	$85,961	$68,504	$53,764

Reagent revenues for 2005 and 2004, respectively, in our Commercial Operations segment are net of $1,278 and $519 of amortization of the non-cash sales discount related to the Quest warrants (see Note 7 above).

The tables below disclose certain other selected segment information:

	2005	2004	2003
Depreciation and amortization			
Commercial Operations	$5,018	$4,698	$ 4,154
TriPath Oncology	266	240	228
Total consolidated depreciation and amortization	$5,284	$4,938	$ 4,382
Amortization of deferred R&D funding from BD recorded as an offset to R&D expense for TriPath Oncology	$ —	$ (207)	$(2,479)
Purchases of property and equipment			
Commercial Operations	$1,133	$1,059	$ 61
TriPath Oncology	455	156	85
Total consolidated purchases of property and equipment	$1,588	$1,215	$ 146
Additions to other intangible assets			
TriPath Oncology	$ 24	$ 319	$ —

	2005	2004
Segment assets		
Commercial Operations	$125,845	$100,717
TriPath Oncology	1,669	1,035
Total segment assets	$127,514	$101,752
Reconciling item		
Inter-segment loan account	(50,546)	(34,218)
Total consolidated assets	$ 76,968	$ 67,534

During 2001, our TriPath Oncology segment received $6,198 in deferred R&D funding from BD, which was amortized as an offset to R&D expenses over thirty months on a straight-line basis. This deferred R&D funding was fully amortized as of January 31, 2004 (see tables above).

Geographic Area Data

Our Commercial Operation's domestic revenues are generated primarily by direct sales activities. The segment initiated expansion of its field sales forces in September 2004, targeted primarily towards our pursuit of additional business under our agreements with large commercial laboratories. International revenues continue to be derived primarily through distributors, except in Canada where we sell directly to our laboratory customers. Revenues by geographic area (or country) are reflected in the tables below:

	2005		2004		2003	
United States	$64,648	75%	$49,663	72%	$39,491	73%
International	21,313	25%	18,841	28%	14,273	27%
Total Revenues	$85,961		$68,504		$53,764	

	2005	2004	2003
International Revenues			
Europe	$ 7,842	$ 8,177	$ 6,087
Canada	7,719	6,425	5,524
Asia	5,479	3,883	2,376
Rest of world	273	356	286
Total international revenues	$21,313	$18,841	$14,273

Revenues are attributed to countries based on the location of our customers, which include both distributors and end-users.

9. Related Party Transactions

We had 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 $0, $28 and $46 during 2005, 2004 and 2003, respectively. 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. We also recovered certain R&D expenses from BD, which were incurred by TriPath Oncology on behalf of BD in terms of our arrangement with BD. These recoveries were set-off against R&D expenses in our TriPath Oncology segment and amounted to $0, $982 and $3,156 in 2005, 2004 and 2003, respectively.

10. Employee Benefits

We maintain a qualified 401(k) Retirement Plan covering substantially all employees that provides for voluntary salary deferral contributions. Total expense for the plan, including employer contributions, amounted to $504, $405 and $435 during 2005, 2004 and 2003, respectively.

Since January 1, 2002, we began offering to employees a qualified Employee Stock Purchase Plan covering substantially all employees that provides 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 2005, 2004 or 2003.

11. Contingencies

We are the exclusive licensee of certain intellectual property used in our molecular diagnostic products. Royalty expenses are based upon contractually agreed-upon minimums. Sales of products that contain this intellectual property above these minimum levels are subject to additional royalty payments based upon the terms of the respective agreements. In connection with the licenses, royalty expenses for the year ended December 31, 2005 were $99.

We compete with Cytyc Corporation (Cytyc) with respect to the sale of our FocalPoint and Cytyc's sale of its ThinPrep Imaging System. We believe Cytyc's ThinPrep Imaging System infringes our patents. In 2003 we filed a lawsuit seeking damages and injunctive relief to stop such infringement and, Cytyc filed a separate action seeking a declaratory judgment in their favor. On January 5, 2004, those suits were consolidated into a single action in the United States District Court for the District of Massachusetts. The case numbers for the consolidated action are 1:03-CV-12630-DPW and 1:03-CV-11142-DPW. The case numbers are for reference only and the corresponding pleadings are expressly not incorporated into this document by reference. Fact and expert discovery have been completed. A claim construction or Markman ruling was issued by the court on November 28, 2005. The court has entered a scheduling order setting forth certain deadlines through June 2006, including those for conducting mediation and filing of summary judgment motions. We anticipate that a trial will be scheduled sometime in late

2006 or the first half of 2007. We are unable to predict the ultimate outcome. Similarly, we are unable to predict the potential effect on our business and results of operations that any outcome may ultimately have.

Furthermore, 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.

12. Change in Accounting Estimate

Effective October 1, 2005 we increased the estimated salvage value of our FocalPoint instruments from $0 to $60 per instrument. We believe the revised amount reflects the historical experience and more appropriately reflects the salvage value of these assets. This change in accounting estimate decreased 2005 depreciation expense by approximately $170. This change in estimate increased diluted earnings per share by $0.01 in 2005.

13. Quarterly Results of Operations (Unaudited)

2005	March 31	June 30	September 30	December 31
Revenues	$19,327	$21,253	$21,525	$23,856
Gross profit	13,548	14,739	15,176	16,463
Net income	925	1,515	1,779	2,281
Earnings per common share (1)				
Basic	$ 0.02	$ 0.04	$ 0.05	$ 0.06
Diluted	$ 0.02	$ 0.04	$ 0.05	$ 0.06

2004	March 31	June 30	September 30	December 31
Revenues	$15,510	$16,721	$18,028	$18,245
Gross profit	10,598	11,720	12,499	12,457
Net (loss)/income	(884)	203	978	308
Earnings/(loss) per common share(1)				
Basic	$ (0.02)	$ 0.01	$ 0.03	$ 0.01
Diluted	$ (0.02)	$ 0.01	$ 0.02	$ 0.01

(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 10.30

TriPath Imaging, Inc. 2006 Bonus Plan

On January 26, 2006, the Compensation Committee of the Board of Directors of TriPath Imaging, Inc. (the "Company") approved the terms of a bonus plan for fiscal year 2006 (the "2006 Bonus Plan"). All employees (other than employees who are covered by a sales compensation or commission-based plan) are eligible to participate in the 2006 Bonus Plan, including all of the Company's executive officers.

Under the 2006 Bonus Plan, the payment of bonus compensation, if any, will be based on the achievement of objective corporate goals. The objective corporate performance goals for each participant will be based on the Company's 2006 revenues, as well as quarterly and annual earnings per share. Bonuses will be payable in cash, options or a combination thereof.

Under the 2006 Bonus Plan, the potential payout of bonus compensation may range from 0% to a maximum of 100% of the bonus target. The bonus target for participants in the 2006 Bonus Plan will be based on a percentage of base salary dependent on the level of responsibility within the Company. The bonus target for each of the Company's executive officers is set forth below.

Executive Officer	Bonus Target (% of Base Salary)
Paul R. Sohmer, M.D. President and Chief Executive Officer	60%
Stephen P. Hall Senior Vice President, Chief Financial Officer	40%
Ray W. Swanson, Jr. Senior Vice President of Commercial Operations	50%
Johnny D. Powers, Ph.D. Senior Vice President and General Manager of TriPath Oncology	50%

Exhibit 10.31

TRIPATH IMAGING, INC.

DIRECTOR COMPENSATION

On January 26, 2006, the Compensation Committee approved a director compensation package for non-management directors who beneficially own less than 3% of the Company's outstanding common stock, to be effective January 1, 2006. The chairs of the Company's Compensation Committee and Nominating and Governance Committee will each receive an annual fee of $5,000, payable quarterly, for service as committee chair. The chair of the Company's Audit Committee will receive an annual fee of $8,000, payable quarterly, for service as committee chair. The lead independent director of the Company will receive an annual fee of $25,000 for service as such. Non-management directors will each receive $18,000 per year for service as a director, payable quarterly, plus a per board meeting fee of $2,500 and a per committee meeting fee of $1,000, plus reimbursement of reasonable expenses incurred in connection with attending or otherwise participating in meetings of the directors and committees of the board.

Non-management directors who beneficially own less than 3% of the Company's outstanding common stock receive compensation for their service on the board pursuant to the Company's 1997 Director Stock Option Plan.

Exhibit 21.1

TRIPATH IMAGING, INC.

LIST OF SUBSIDIARIES

Name of Subsidiary	State or Jurisdiction of Incorporation or Organization
TriPath Oncology, Inc.	Delaware
AutoCyte NC, LLC	North Carolina
AutoCyte Australia Pty Ltd	Australia
Cell Analysis Systems, Inc.	Illinois
TriPath Imaging Europe bvba	Belgium

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement Nos. 333-41465, 333-41467, 333-74936, 333-88611, 333-91306, 333-116274, 333-116275, and 333-74938, each on Form S-8, of our reports dated February 17, 2006, with respect to the consolidated financial statements of TriPath Imaging, Inc., TriPath Imaging, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of TriPath Imaging, Inc. included in the Annual Report on Form 10-K of TriPath Imaging, Inc. for the year ended December 31, 2005.

/s/ ERNST & YOUNG LLP

Raleigh, NC
February 28, 2006

Exhibit 31.1

Certification Pursuant to Section 240.13a-14 or 240.15d-14 of the Securities Exchange Act of 1934, as amended

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Paul R. Sohmer

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

Date: February 28, 2006

Exhibit 31.2

Certification Pursuant to Section 240.13a-14 or 240.15d-14 of the Securities Exchange Act of 1934, as amended

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Stephen P. Hall

Stephen P. Hall
Chief Financial Officer

Date: February 28, 2006

Exhibit 32

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350

Each of the undersigned officers of TriPath Imaging, Inc. (the "Company") certifies, under the standards set forth in and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of the Company for the year ended December 31, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in that Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Paul R. Sohmer

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

Dated: February 28, 2006

/s/ Stephen P. Hall

Stephen P. Hall
Chief Financial Officer

Dated: February 28, 2006

EXHIBIT 99.1

TRIPATH IMAGING, INC.

FACTORS AFFECTING FUTURE OPERATING RESULTS

February 2006
(dollar amounts in thousands)

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 molecular diagnostic reagents and imaging systems are at an early stage of development and we cannot assure the successful development or the commercial success of these products.

Our oncology products, including our molecular diagnostic reagents and imaging systems, are in the early stages of development and significant additional research, development, clinical studies, 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 reagents and imaging systems for a variety of cancers that incorporate genomic or proteomic markers we received through our collaboration with Becton, Dickinson and Company, or BD, as part of the strategic alliance between BD and Millennium Pharmaceuticals, Inc., or Millennium as well as other genomic or proteomic markers that have been or may be identified independently of that agreement. We may fail to successfully develop and commercialize our oncology products if:

- 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 molecular oncology products, our revenues could be adversely affected.

Our products are subject to FDA review, approval and regulation and which may prevent us from commercializing any of our products currently in development.

The FDA extensively regulates the manufacture and sale of medical diagnostic devices for commercial use. For example, we must comply with applicable FDA regulations, which can include prospective FDA approval or clearance of products before we can market and sell them for their intended uses in the United States.

To obtain FDA approval or clearance of our device products, we must submit a pre-market approval application, or PMA, or notification for 510(k) clearance, depending on the controls required by 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 or clearance 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 or clearance for any of our future products, if FDA approval or clearance 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 or clear our future products for their intended use. In addition to the pre-market approval or 510(k) clearance processes, 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 or clear our future products or commercial enhancements to our existing products on a timely basis, if at all. To the extent our molecular diagnostic products are intended for use as prognostic tests in selecting subsets of patients most likely to benefit from drug therapies, development and approval of those products may be dependent upon investigation in drug clinical trials and obtaining approval to include the device in the labeling of the drug for which its use is intended. Our regulatory applications also may be delayed or rejected based on changes in regulatory policies or regulations.

Some of our molecular diagnostic reagents will be sold as analyte specific reagents (ASRs). FDA defines ASRs as antibodies, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which through specific binding or chemical reaction with substances in a specimen are intended to use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. In simple terms, an ASR is the active ingredient of an in-house laboratory test that is used in conjunction with other general purpose reagents and general purpose instruments by a laboratory that is certified as high complexity under the Clinical Laboratory Improvement Act of 1998 as amended (CLIA) to set up an in-house ("home brew") test or laboratory testing service. While specimens can travel to the lab setting up this service, the test itself cannot be marketed outside of the single lab setting up this service, nor can clinical claims be made outside of those validated and communicated by the single lab performing the "home brew" test. It is the responsibility of the laboratory using the ASR to develop a recipe for the test at hand and to take responsibility for establishing and maintaining performance. Our interactions with the laboratories that purchase our ASRs are limited and out interactions with their referring clinicians are restricted, therefore, the onus is on the laboratory to develop, validate and promote the test as well as demonstrate its clinical efficacy. If laboratories are unable to effectively develop, validate and promote "home brew" tests, our ability to sell these ASRs will be limited.

Our products are subject to review, approval and regulation by foreign regulatory agencies which may prevent us from commercializing any of our products currently in development.

Foreign regulatory agencies may regulate the manufacture and sale of medical diagnostic devices for commercial use in countries other than the U.S. We must comply with these foreign regulations, which may vary from country to county and may vary from those required by the FDA. These can include prospective approval of products before we can market and sell them for their principal intended uses in certain international markets.

Sales of our products in the EEA are subject to strict regulatory requirements and approval is never certain. Effective December 7, 2003, all of our products are required to comply with the European *In Vitro* Diagnostics Medical Devices Directive (IVDD) and bear the CE mark before being imported for sale in the EEA. The CE mark is a symbol indicating that the device conforms to the essential requirements of the applicable directive, and can be commercially distributed throughout the EEA. The IVDD also subjects our manufacturing facilities to compliance inspections, and requires design, manufacturing and quality process documentation and controls. Some of our products do not currently bear the CE mark. We cannot be certain that the CE mark will be granted for all our products, or that regulatory review will not involve delays that would adversely impact on our ability to market and sell our products in the EEA.

The regulatory requirements outside the United States usually impose pre-market review or approval requirements for our products and considerations similar to those in the United States apply.

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

Any products approved by the FDA or foreign regulatory agencies are still subject to continual government review and regulation, so long as the product is being marketed. Our cervical cytology products, PrepStain, FocalPoint and the use of PrepStain with FocalPoint, have received FDA approval, are CE marked and are approved for sale in the EU under the IVDD. Although we have received regulatory approvals, we are still subject to continual regulatory 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 or 510(k) applications;
- suspension or withdrawal of our FDA approvals or clearances;
- product recalls;
- customer notification, or orders for repair, replacement or refunds;
- operating restrictions, including total or partial suspension of production, distribution, sales and marketing of our products;
- customer notification, or orders for repair, replacement, or refunds;
- injunctions; or
- product seizures; and
- criminal prosecution of us, our officers or our employees.

Similar considerations apply outside the United States.

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. 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 diagnostic methods and/or treatments for cancer.

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 clinical impact, accuracy and analytical performance, all-in cost, including our material charges to the laboratory as well as the laboratory's labor and overhead costs related to the adoption of our products, processing speed and reliability, convenience, and perception among consumers, influential opinion leaders, clinicians, laboratories, payors, regulatory agencies, patient advocacy groups and clinical governing bodies and associations. To effectively compete, we must keep pace with the product development and technological change in our industry. Our products must demonstrate clinical efficacy, analytical performance and cost effectiveness that equals or exceeds that of competing products and technologies. We cannot guarantee that our products will be competitive in any of these areas.

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

Sales of SurePath reagents and disposables and sales, rentals, and usage fess associated with PrepStain and FocalPoint currently account for the substantial majority of our revenues. Market acceptance of SurePath, PrepStain and FocalPoint, as well as their combined use, will depend on our ability to convince clinical laboratories, physicians, third party payors, other health care providers and consumers that our products can address the limitations of the conventional Pap smear process and demonstrate clinical efficacy, analytical performance and cost effectiveness that equals or exceeds that of competing products. We may not be able to successfully establish that our products are better and more cost effective when compared to the conventional Pap smear or our competitors' products and, as a result the market may not accept our cervical cytology products as a replacement for the conventional Pap smear or as an alternative to our competitors' products. Even if SurePath, PrepStain, and FocalPoint 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, Medicare, and Medicaid and other government healthcare providers. There can be no assurance that we will achieve greater market acceptance for SurePath, PrepStain, or FocalPoint, 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 molecular diagnostic products or imaging systems that we develop. While various diagnostic methods for cancer are currently available, few tests offer an integrated solution for diagnosing cancer at the earliest possible stage that provides individualized predictive and prognostic information, guides treatment selection for patients with cancer, and predicts disease recurrence. Market demand for any

molecular diagnostic products that we develop will depend primarily on acceptance by clinical laboratories, physicians and third party payors and endorsement by influential opinion leaders, clinical governing bodies and associations, patient advocacy groups, and consumers. Commercial acceptance of our molecular diagnostic tests and imaging systems, if any, will depend upon several factors, including:

- their potential clinical advantages, including their impact on patient management, impact on patient outcome, impact on the costs of patient care, and cost benefit and effectiveness relative to alternative diagnostic methods;
- product features that facilitate their adoption by laboratories, including accuracy, reproducibility and other indicators of analytical performance, all-in cost, including our material charges to the laboratory as well as the laboratory's labor and overhead costs related to the adoption of our products, impact on laboratory organization and staffing, processing speed and reliability, convenience, complexity of result interpretation, and cost effectiveness relative to alternative diagnostic methods;
- our ability to design and execute clinical trials whose results demonstrate the clinical value of our products, provide us a basis for communicating the clinical value of our products and translate into market opportunity;
- 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 any of the molecular diagnostic products that we develop do not achieve significant market acceptance, it could have a material adverse effect on our business, financial condition and results of operations.

We have a history of operating losses and an accumulated deficit and we may not remain profitable.

We have a history of operating losses. While we became profitable for the first time in 2004 and were profitable for 2004 and year-end 2005, we intend to continue to market our products, develop new products and perform additional clinical studies, all of which will continue to be a drain on earnings. While our cervical cytology and slide wizard product lines have grown in acceptance as measured by our revenues, we still operate in a very competitive environment. Additionally, we have yet to achieve market acceptance of our molecular diagnostic products and product candidates. As of December 31, 2005, we had cumulative net losses of $225,915. These losses resulted principally from the costs of our research and development and sales and marketing activities and other 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 and 510(k) applications to the FDA.

We expect marketing and sales expenses, as well as regulatory expenses, associated with our products to either continue at their current rate or increase in the future, which could burden our drive toward continued profitability. These expenses are a result of our expanded marketing and sales efforts to continue the commercial rollout of our products and our efforts to obtain FDA and other approvals for our products. Our continuing profitability is subject to uncertainty and will depend on a number of factors including:

- receipt of regulatory approvals or clearances for future products in a timely manner;
- successful marketing of our products in the United States and abroad;
- 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;
- the timing of certain non-cash sales discounts relating to warrants held by Quest, which depend upon the achievement of certain sales-based milestones;
- availability of reimbursement from third-party payors, and the extent of coverage;
- ability to establish internal financial controls and other infrastructure necessary to support large-scale commercial operations; and
- the impacts of the provisions of SFAS 123(R) and the ultimate realization of our income tax loss carryforwards on our financial results.

We expect to continue our profitable performance into 2006, anticipating that product sales and service revenues will sufficiently fund our operations while our oncology business is developing products that can be commercially introduced into the market. While we hope that 2006 will be profitable as a whole, we cannot be certain that we will achieve profitability.

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 primarily through the private placement and public sales of equity securities, debt facilities and product sales. We have had negative annual cash flow from operations since inception. During the last half of 2004, we experienced positive cash flow from operations for the first time. At December 31, 2005, we had $22,457 in cash and cash equivalents. While we believe that we will continue to achieve overall corporate profitability in 2006, there is no certainty that we will be able to maintain profitability and/or positive cash flows from operations. In any event, we believe that our existing cash and existing debt and lease financing will be sufficient to enable us to meet our future operating cash obligations for the foreseeable future.

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 will significantly limit our ability to continue our operations.

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

- our ability to maintain profitability;
- the timing and costs of product introductions;
- the extent of our ongoing research and development programs, including those 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 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 corporate relationships are unsuccessful, our earnings growth will be limited.

An important element of our strategy is to enter into corporate relationships for the research and development of alternative applications for our extensive body of intellectual property and, where appropriate, for the market introduction of some of our new products. We currently have a corporate relationship with BD for the development of diagnostic and pharmacogenomic oncology tests and with Ventana to sell and distribute a Ventana branded version of our interactive histology imaging system. We may enter into additional corporate relationships in the future. We believe that recent advances in genomics, biology, and informatics are providing new opportunities to leverage our proprietary technology and that some of our products appeal to markets that are better served by other companies. The success of these arrangements is largely dependent on technology and other intellectual property contributed by our collaborators or their market position and selling and distribution strength, as well as their efforts, resources and skills. Our existing and future corporate relationships are also dependent upon our collaborators" continued willingness to work with us, as opposed to our competitors and to prioritize their projects with us. There can be no assurance that we will succeed in implementing and finalizing any new corporate relationships to facilitate the exploitation of our intellectual property estate or to augment our sales and distribution activities. The failure to do so could have a material adverse effect on our future prospects inside and outside of the cervical cytology or molecular diagnostic markets and could impact our business, 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 SurePath, PrepStain and FocalPoint, and related products as well as our molecular diagnostic reagents and imaging systems at either our Burlington, North Carolina, or our Redmond, Washington facilities. Currently, we have limited manufacturing experience in 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 and molecular diagnostic 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, if and when needed , or successfully contract with third parties to manufacture our products, our business and 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 including PrepStain and FocalPoint components, 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 supplemental submissions to the FDA for its approval or clearance 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 or clear these new components quickly, if at all.

If we do not successfully expand our marketing and sales resources, we may not be able to maintain profitability.

We are currently expanding our marketing and sales forces to more effectively market our cervical cytology products. Further, it is our intent to channel our molecular diagnostic products through this expanded marketing and sales force, when appropriate. Even with the increased size of our sales force, we may not be able to successfully promote our cervical cytology or molecular diagnostic products to clinical laboratories, health care providers, including physicians, and third-party payors or penetrate the large commercial laboratory segment to the extent anticipated. In addition, we must continue to educate health care providers and third-party payors regarding the clinical benefits and cost-effectiveness of our cervical cytology and molecular diagnostic 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. In addition, we find that our current marketing and sales force cannot effectively market our molecular diagnostic products forcing us to seek an alternative approach.

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 have experienced growth in our employee base and in the scope of our operations, and we anticipate that further expansion may 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 recent years, 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 in its current form or any future form will be able to continue to work together effectively or manage our growth successfully. We believe that the successful integration of any new members of management that we may hire, and cooperation of our existing 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 110 issued or allowed U.S. patents. We also hold approximately 40 foreign patents and have applied for patent protection for certain aspects of our technology in various foreign countries. Most of our existing U.S. and foreign patents will expire between 2012 and 2020. In addition, our molecular diagnostic reagents incorporate genomic or proteomic markers we received through our collaboration with BD as well as other genomic or proteomic markers that have been identified independently of that agreement. Our approach to marker discovery, identification, and prioritization is based on correlation with patient outcome and includes the evaluation of markers that have been previously identified by others as well as novel markers that have not been previously associated with our specific product indications. As a result, to ensure our freedom to utilize known markers and integrate them into our product candidates, we will in certain instances be required to license them from third parties. We are concurrently pursuing intellectual property protection for the novel markers that we have identified and the proprietary formulations that we are creating from the combination of either novel or known markers as well as for molecular imaging systems. However, we cannot be sure that we will be able to license markers on acceptable terms, if at all, or establish intellectual property protection of our novel markers, proprietary formulations or molecular imaging systems which could make the possibility of piracy of our technology more likely.

Our reliance on patents poses the following risks:

- any patent applications that we file 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.

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 U.S. 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.

As of March 2006, we are engaged in patent litigation with one of our largest competitors, Cytyc Corporation. In this proceeding, we are claiming among other things that Cytyc's ThinPrep Imaging System infringes certain of our patents. Cytyc is claiming that its product does not infringe our patents and that certain of our patents are invalid. See "Legal Proceedings" in our Annual Report on Form 10-K for the year ended December 31, 2005, as well as any updated in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K for the current fiscal year.

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

In addition, 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.

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 and except for Canada, where we sell through our own direct sales force, we market and sell our products outside the U.S. primarily through a network of regional distributors. Our success in most international markets is, to a large extent, dictated by the performance of our regional distributors. 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. There can be no assurance that we will effectively manage our network of independent regional distributors. 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. Roche Holdings, Inc., our largest shareholder, owns approximately 20% of our shares. If Roche sells all or a significant portion of these shares, our stock price may decline.

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 2006, Roche beneficially owned approximately 20% of our outstanding common stock. Roche also has the right to designate one member of our Board of Directors. In addition, as of March 2006, 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, national, state or local 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 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, Medicare and Medicaid and government healthcare providers. Virtually all of our revenues will be dependent on customers who rely on third party reimbursement. Third-party healthcare payors in the United States and elsewhere 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.

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.

As with our cervical cytology products, our molecular diagnostic reagents and imaging systems will be primarily purchased by medical institutions and laboratories that bill third-party payors such as government healthcare administration authorities, private health coverage insurers, managed care organizations and other similar organizations. Our ability to earn sufficient returns on these products will depend in part on the extent to which reimbursement for these products and related treatments will be available to our customers from third-party payors. All of our slide based molecular diagnostic reagents are being formatted as either immunohistochemistry or immunocytochemistry tests that may be performed either with or without image analysis. Currently, generic billing codes and reimbursement schedules exist for these technologies, with and without image analysis, and the opportunity exists to enhance third party reimbursement if the results of clinical studies support unique and high value clinical claims. For blood based screening assays, we will most likely be required to work with government healthcare administrative authorities to establish new billing codes and reimbursement schedules. Under any circumstance where we are applying for new codes, the process is time consuming, there can be no guarantee we will obtain the new code, and if and when we do obtain the new code, that the majority of our customers will be successful to obtain reimbursement at the levels specified by the code from their payor population. Third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of products to contain costs, and if they are successful, our ability to generate revenue growth and profitability from our molecular diagnostic products will be adversely effected.

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 clinicians, laboratorians and other health care providers on, and convince them of, the clinical benefits and cost-effectiveness of our products; and
- demonstrate to clinicians, laboratorians and other 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 to the extent that we anticipate. Even if we do successfully sell our products to large clinical laboratories, those sales may not generate enough revenue to maintain our profitability.

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 in particular 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.