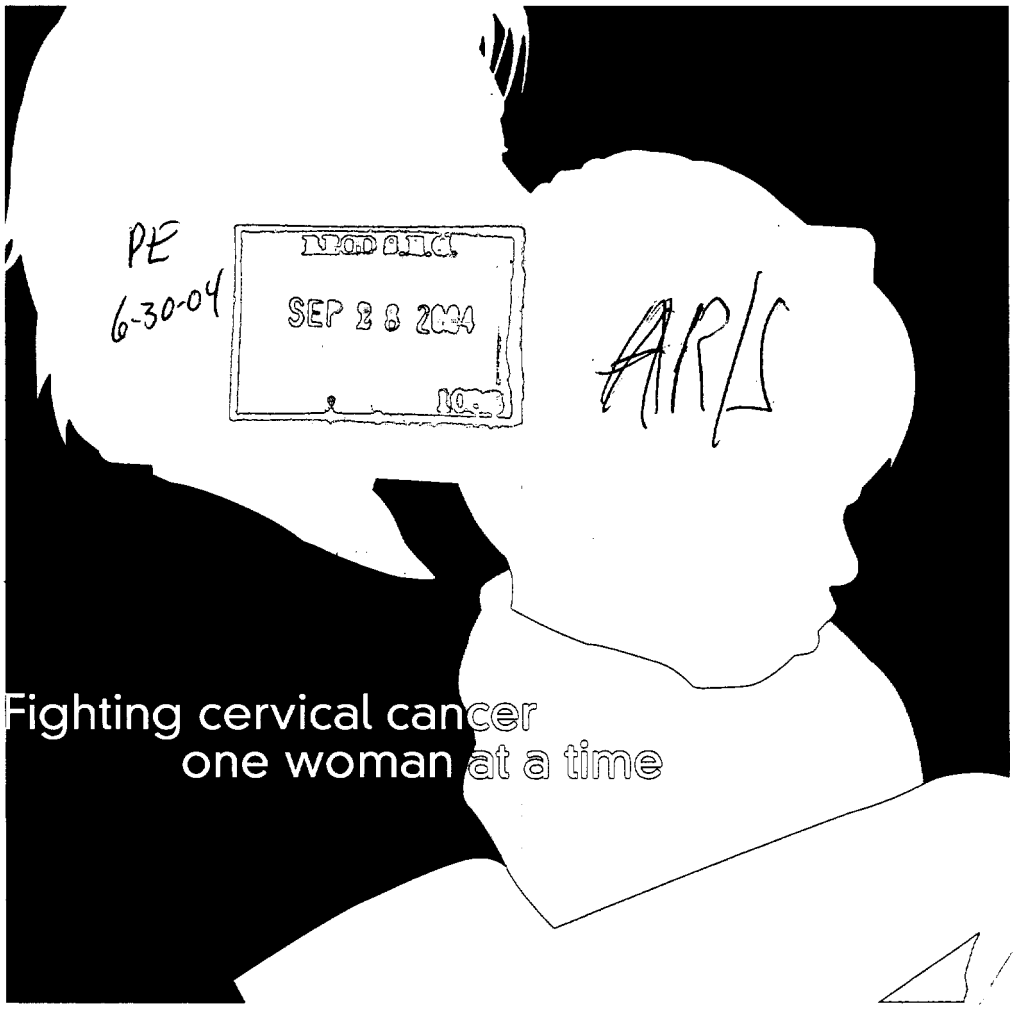
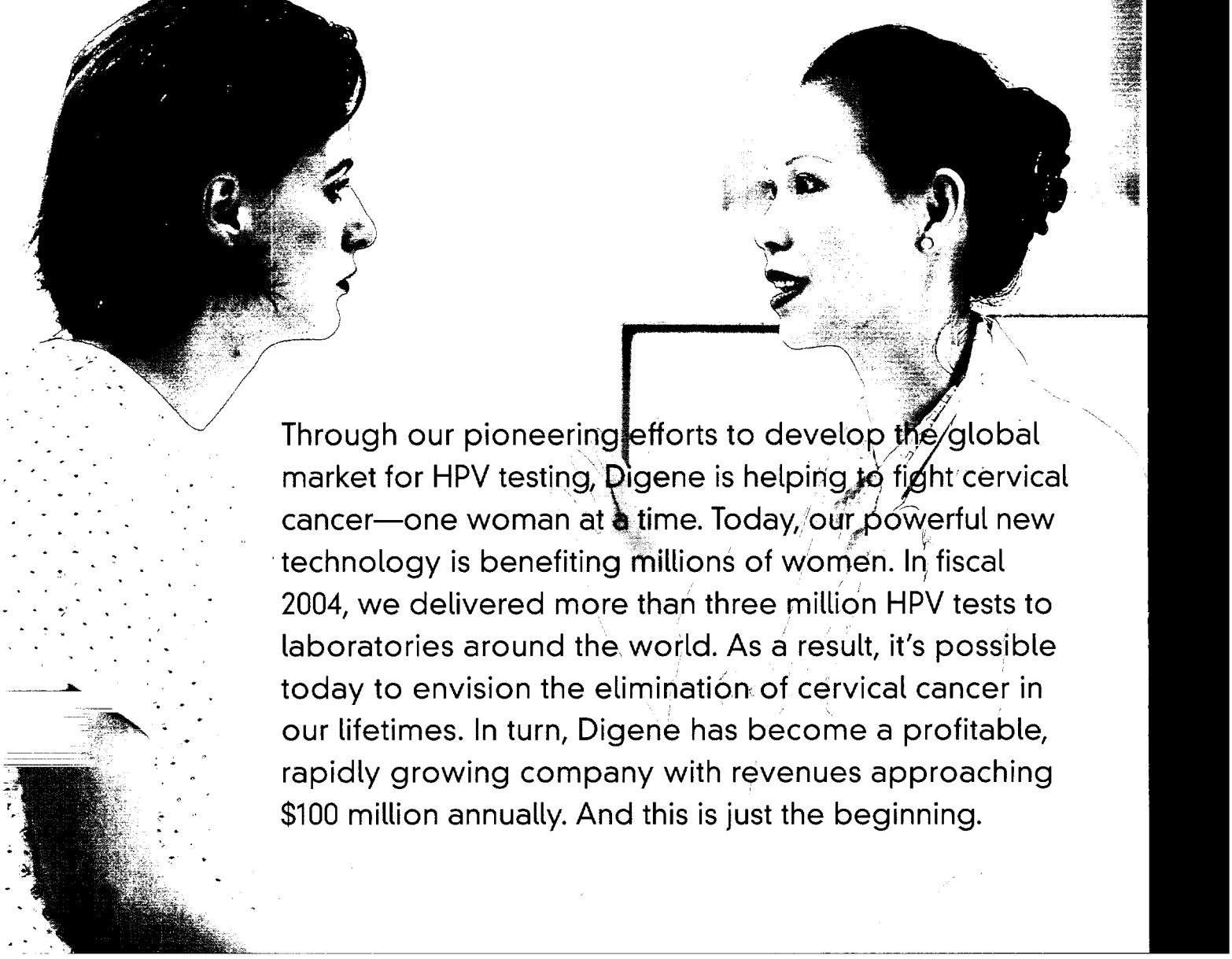


DIGENE

2004 ANNUAL REPORT



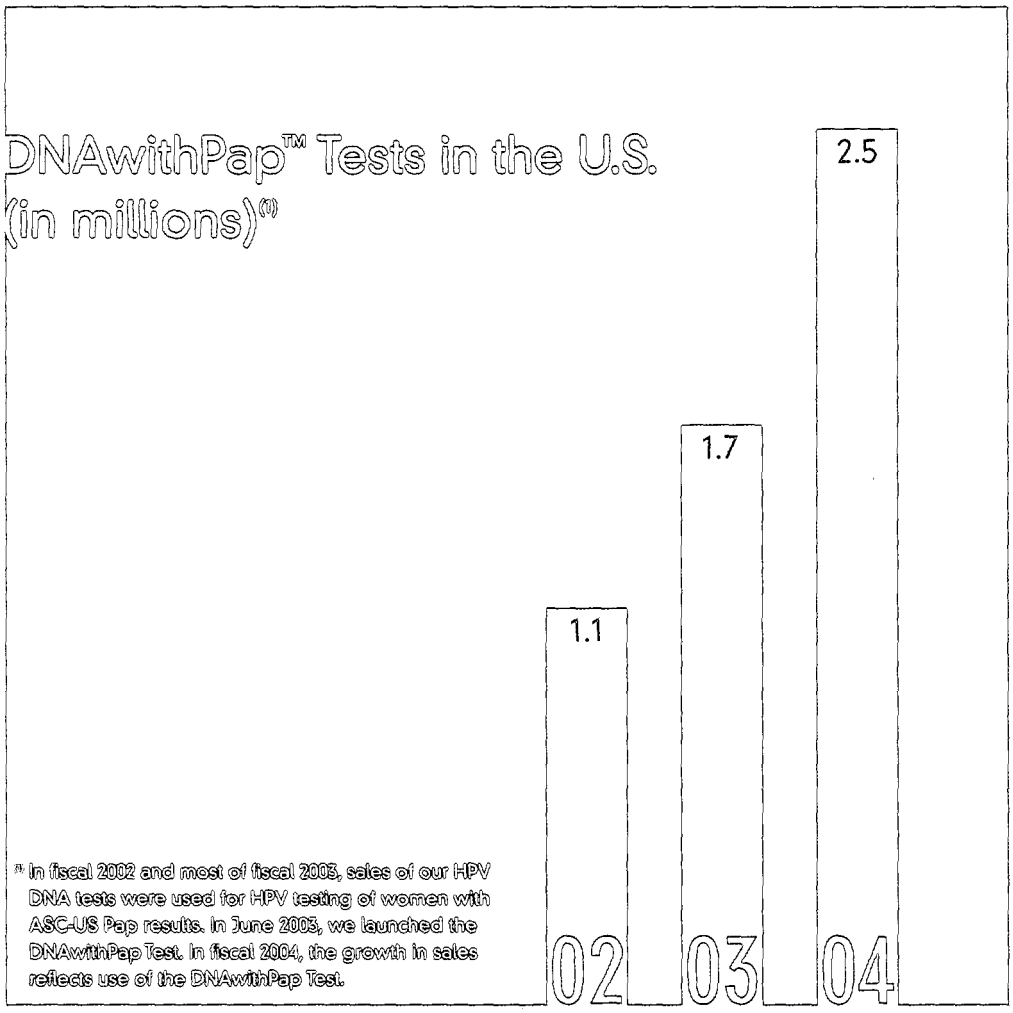
Through our pioneering efforts to develop the global market for HPV testing, Digene is helping to fight cervical cancer—one woman at a time. Today, our powerful new technology is benefiting millions of women. In fiscal 2004, we delivered more than three million HPV tests to laboratories around the world. As a result, it's possible today to envision the elimination of cervical cancer in our lifetimes. In turn, Digene has become a profitable, rapidly growing company with revenues approaching $100 million annually. And this is just the beginning.

Financial Highlights

(In thousands)

Year Ended June 30,	2000	2001	2002	2003	2004
Total Revenue	$23,044	$34,197	$48,848	$63,102	$90,161
Gross Margin	$14,368	$20,153	$32,812	$49,057	$72,098
Worldwide HPV Test Revenue	$10,019	$19,495	$34,034	$51,114	$74,581
Income before Income Taxes	$(6,583)	$(6,364)	$ (9,187)	$(4,100)	$ 7,217
Net Income	$(6,767)	$(6,481)	$ (9,397)	$(4,324)	$ 21,542[1]

[1] Includes recognition of $14.9 million deferred tax benefit.



In fiscal 2004, sales of our HPV DNA tests continued to expand. Use of our test for the triage of women with ASC-US Pap results has become the standard of care in the United States, and the DNAwithPap™ Test was successfully launched as part of routine cervical cancer screening for women age 30 and older.

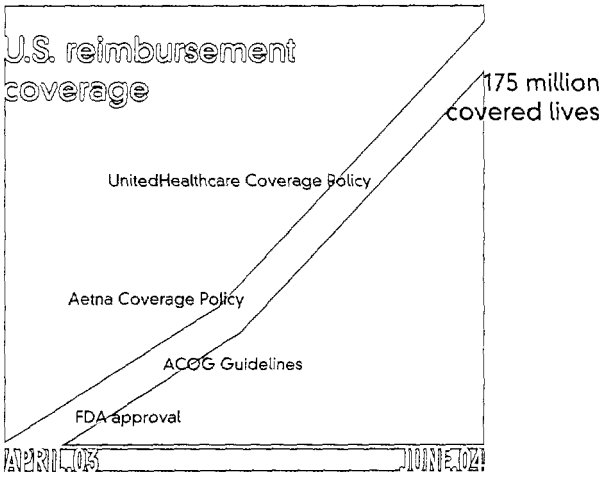
DIGENE

Our goal is to ensure that every woman in the world has access to the DNAwithPap Test.

We are working around the world to broaden access to our tests through major healthcare delivery networks. Securing reimbursement for both ASC-US triage and routine screening is an important part of this effort. Insurance reimbursement for the DNAwithPap Test in the United States increased dramatically during fiscal 2004, with covered lives increasing to approximately 175 million. The test now is covered by major payors in the United States, including Aetna, CIGNA, UnitedHealthcare and the majority of the largest Blue Cross Blue Shield plans. The public health sector also has embraced the DNAwithPap Test, with 27 state Medicaid programs and numerous managed-care programs now providing coverage.

We also are making excellent progress in Europe. In January, the French Ministry of Health approved reimbursement for high-risk HPV testing in the evaluation of women with ASC-US Pap results, leading to rapid test growth during the year. In addition, reimbursement is now available in Switzerland, and countries such as Italy and the Netherlands are close to completing large-scale clinical trials that should support reimbursement coverage for broader indications.

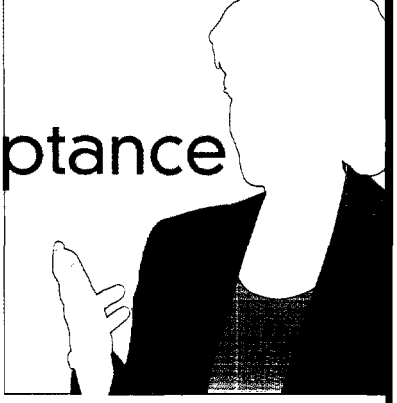
The health challenges of the developing world are also our concern. In January, we entered into a partnership with the Program for Appropriate Technology in Health to develop an HPV test for use in cervical cancer screening in regions with minimal resources and medical infrastructure. Under this collaboration, Digene will develop and manufacture a customized screening test based on our proprietary Hybrid Capture® technology. This effort brings us one step closer to achieving Digene's core mission of ensuring that no woman dies of cervical cancer, no matter where she lives.



"I am a musician, and just as my career was taking off, I found out I had invasive cervical cancer. I had gotten a Pap test every year from the time I was 18, and it had been normal every time. But I learned the hard way that a Pap can falsely appear normal—until it's too late. At that point, everything stopped for me. I had a radical hysterectomy, and my dream of having children evaporated. Now, I'm using my music, and the power of my voice, to educate other women—in concerts, in media interviews and in state legislatures—to ask for an HPV test along with the Pap."

Christine Baze—Musician and Cervical Cancer Survivor

Acceptance



Increasing numbers of medical providers around the world are recognizing the importance of HPV testing as the standard of care in cervical cancer screening.

A significant driver behind the emerging status of our DNAwithPap Test as a standard of care is the recognition of the role HPV testing plays in routine screening by leading professional organizations—including the American College of Obstetricians and Gynecologists, the American Cancer Society, the Association of Reproductive Health Professionals and the World Health Organization. In January, Kaiser Permanente Northern California, one of the nation's leading managed care providers, announced its decision to implement the DNAwithPap Test as a standard of care for all of its women patients age 30 and older. This pioneering program already results in the testing of approximately 300,000 women annually. Women's Health Connecticut, the nation's largest physician group dedicated to women's health, also has established itself as a leader in providing access to routine HPV testing; in January, the DNAwithPap Test became a standard offering throughout the group's offices. These trailblazing practices and plans are models for others.

"While the Pap is a good test, the combination of a Pap and an HPV test is a better approach for women 30 and older. I can be much more certain of the results, and patients appreciate that I am giving them the most advanced screening tests possible."

Mark DeFrancesco, M.D.—Chief Medical Officer, Women's Health Connecticut

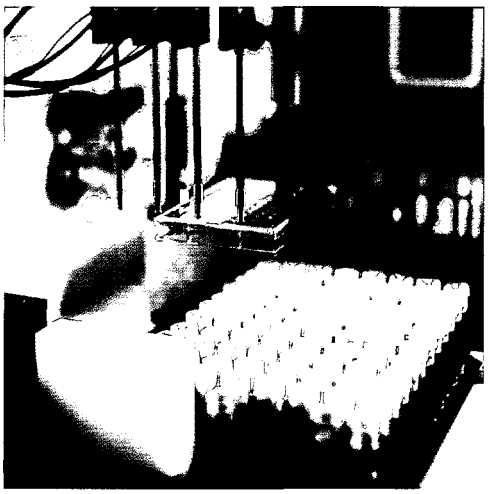
Delivery

Digene's innovative products are reaching more patients through an expanded distribution system in the United States, Europe and beyond.

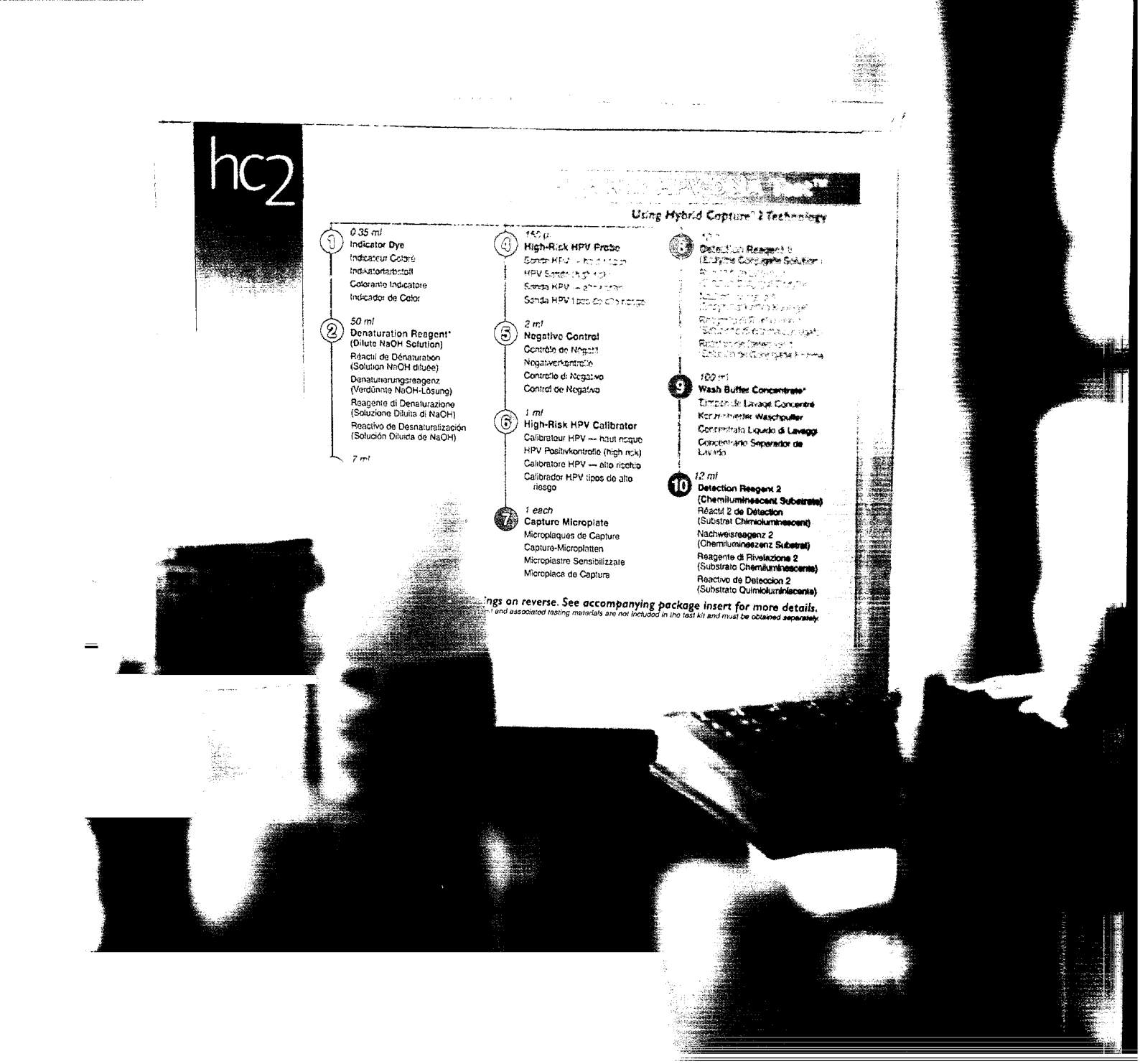
Digene has established strong working relationships with laboratories both large and small, which in turn provide the DNAwithPap Test to physicians and their patients. In August 2003, LabCorp® became the first national reference laboratory to offer its physician customers the DNAwithPap Test. In January 2004, Digene announced a similar, three-year agreement with Quest Diagnostics, the nation's largest commercial testing laboratory. Quest performs more than 12 million Pap tests annually—providing an unparalleled opportunity for expanding the use of the DNAwithPap Test and educating physicians about its benefits. Other leading medical providers that came on board during the year include the Cleveland Clinic, Columbia University and the University of Arizona Health Sciences Center. With this greatly expanded reach, Digene has established a comprehensive distribution system for the DNAwithPap Test in the United States.

To allow our lab partners to achieve greater productivity through high-throughput testing, Digene developed the Rapid Capture® System. In May, the FDA approved our PMA supplement application—leading to another Digene first: the Rapid Capture System is the first high-throughput system for HPV, chlamydia and gonorrhea testing. Using this system, 352 patient specimens can be analyzed by one technologist in a 6.5-hour lab shift. Acceptance of Rapid Capture has been excellent—particularly by large reference labs, where efficiency and productivity are critical.

To accelerate access to HPV testing in Europe, Digene completed the formation of six European sales, marketing and distribution companies during fiscal 2004. Today, a team of more than 60 professionals is dedicated to working with laboratories, healthcare providers and government officials to establish HPV testing for both triage and routine screening in Europe as well as in other regions.



FDA approval and market acceptance of the Rapid Capture System allow millions of HPV tests to be performed quickly and efficiently each year.


hc2
Using Hybrid Capture® 2 Technology
1
0.35 ml
Indicator Dye
Indicateur Coloré
Indikatorfarbstoff
Colorante Indicatore
Indicador de Color
2
50 ml
Denaturation Reagent*
(Dilute NaOH Solution)
Réactif de Dénaturation
(Solution NaOH diluée)
Denaturierungsreagenz
(Verdünnte NaOH-Lösung)
Reagente di Denaturazione
(Soluzione Diluita di NaOH)
Reactivo de Desnaturalización
(Solución Diluida de NaOH)
7 ml
4
150 µl
High-Risk HPV Probe
5
2 ml
Negative Control
Contrôle de Négatif
Negativkontrolle
Controllo di Negativo
Control de Negativo
6
1 ml
High-Risk HPV Calibrator
Calibrateur HPV — haut risque
HPV Positivkontrolle (high risk)
Calibratore HPV — alto rischio
Calibrador HPV tipos de alto riesgo
7
1 each
Capture Microplate
Microplaques de Capture
Capture-Microplatten
Microplastre Sensibilizzate
Microplaca de Captura
8
Detection Reagent 1
9
100 ml
Wash Buffer Concentrate*
Tampon de Lavage Concentré
Konzentrierter Waschpuffer
Concentrato Liquido di Lavaggi
Concentrado Separador de Lavado
10
12 ml
Detection Reagent 2
(Chemiluminescent Substrate)
Réactif 2 de Détection
(Substrat Chimioluminescent)
Nachweisreagenz 2
(Chemilumineszenz Substrat)
Reagente di Rivelazione 2
(Substrato Chemiluminescente)
Reactivo de Detección 2
(Substrato Quimioluminiscente)
ngs on reverse. See accompanying package insert for more details.
and associated testing materials are not included in the test kit and must be obtained separately.

Digene is revolutionizing the way cervical cancer screening is performed throughout the world by establishing its DNAwithPap Test as the new standard of care for cervical cancer screening.

Education and commercialization

We're spreading knowledge in the medical community and to women worldwide about the significant role HPV testing plays in cervical cancer screening.

Education of physicians and women is a critical element of Digene's commercialization strategy for the DNAwithPap Test. In the United States, we established a team of 35 physician-education specialists and conducted continuing medical-education workshops and other programs during the year to spread the word about the benefits of HPV testing and its appropriate use. Other innovative outreach activities included a partnership in which we helped Aetna provide educational materials to more than 13,000 member physicians.

Digene also recognizes the need to educate women about cervical cancer, empowering them with the knowledge they need to ask about HPV testing and break down barriers to access. We have supported Women In Government, a bipartisan, nonprofit educational association for the 1,600-plus elected women in state governments, in the launch of its *Challenge to Eliminate Cervical Cancer Campaign*. The goal of the campaign is to eliminate cancer in the United States in 10 years through education and legislative initiatives designed to broaden access to cervical cancer screening, including new technologies. To date, legislation or resolutions have been introduced or passed in 18 states. Complementing this effort is an initiative sponsored by the Coalition of Labor Union Women to educate the nation's 7.5 million union women, as well as female family members of male union members, on the importance of regular cervical cancer screening, including HPV testing. Going forward, these organizations will be joined by The Balm in Gilead, a faith-based, African-American organization originally founded to help stop the spread of HIV/AIDS, which will now expand its programs to include cervical cancer screening and HPV testing. These efforts and others that enlist women as partners in their own healthcare will further help establish HPV testing and the DNAwithPap Test as the standard of care in the United States and around the world.

"The introduction of HPV testing is greatly facilitated by the education of healthcare providers, their staff and the women they care for. Digene is a leader in responsible HPV education for both patients and providers. Its efforts have included sponsorship of regional medical education courses designed to educate clinicians in all aspects of women's care, demonstrating the company's strong commitment to the entire well-being of women."

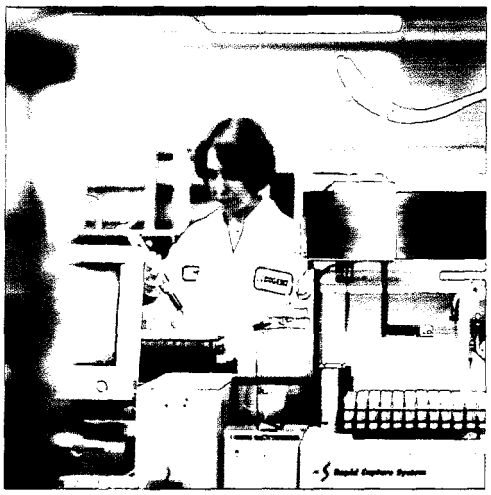
J. Thomas Cox, MD—Director, Women's Clinic, University of California Santa Barbara

A world-class organization

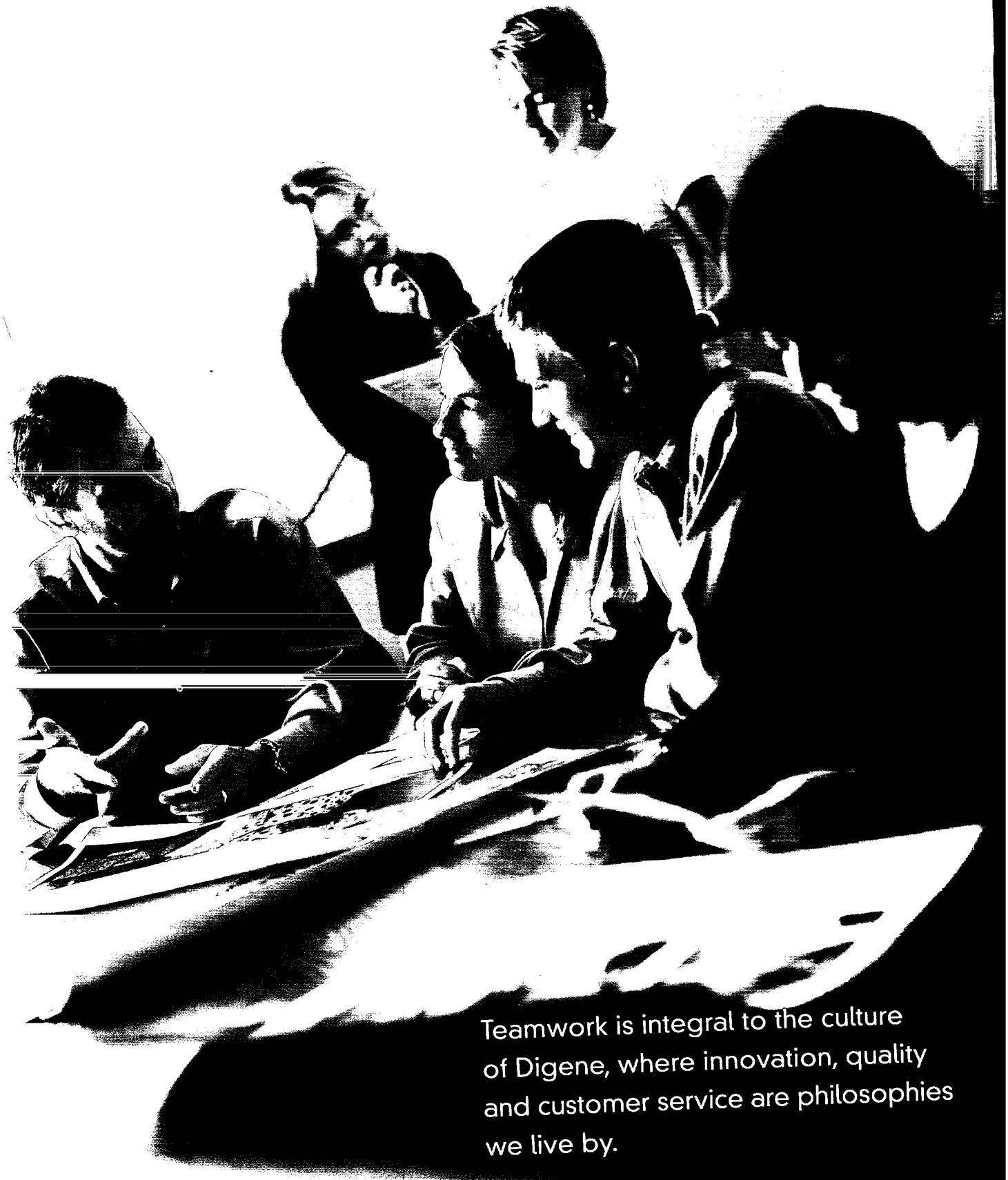
Approval of the DNAwithPap Test has transformed Digene from a successful molecular diagnostic company to a world-class cervical cancer screening company.

With its commitment to improving women's health diagnostics, Digene has developed into a premier cancer-screening company. Our organization of approximately 400 professionals is committed to excellence in research, development, marketing and related disciplines. This team has built a global market for HPV testing, and additional innovations are in development.

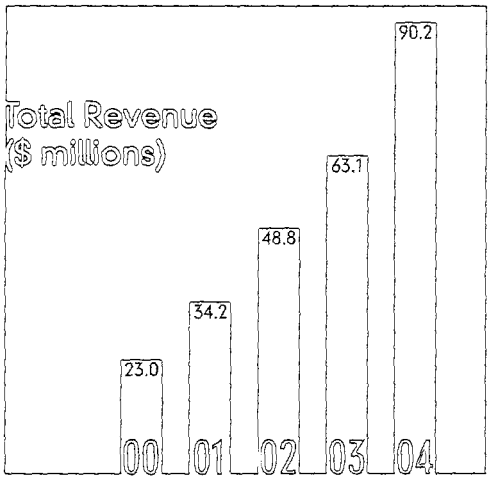
With our global sales and marketing team approaching 150 professionals, we have established direct sales capabilities in the United States and major European countries. Today, our proven distribution network reaches throughout the industrialized world. Collectively, these capabilities provide Digene with a unique commercial platform and opportunity to develop, manufacture and market innovative women's health diagnostic products.

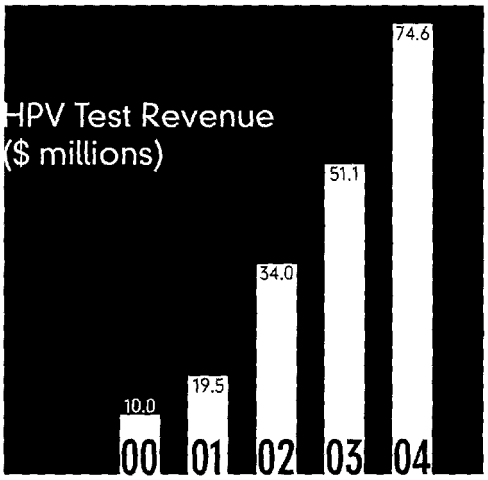


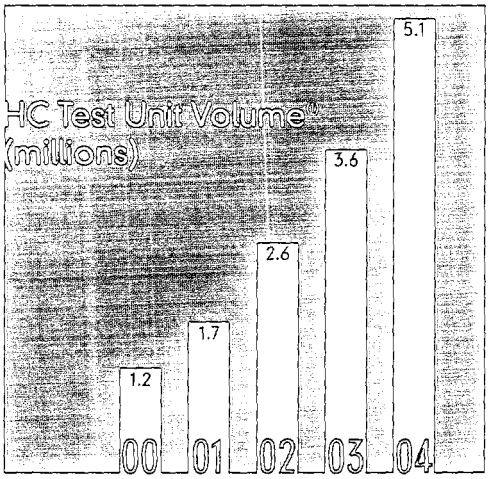
One of our key goals is to continually expand our core technology and expertise in molecular diagnostics in order to remain at the forefront of DNA testing for cervical cancer and to develop new diagnostic tests for unmet medical needs.



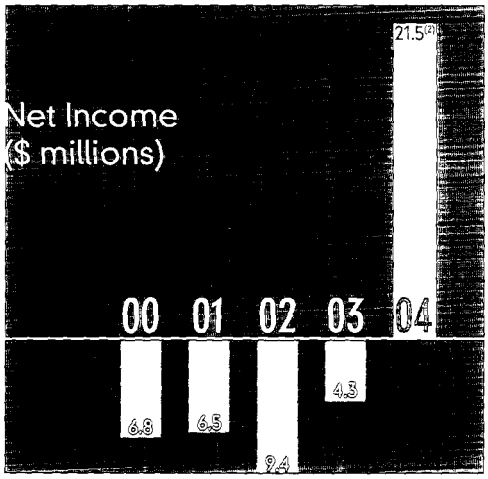
Teamwork is integral to the culture of Digene, where innovation, quality and customer service are philosophies we live by.







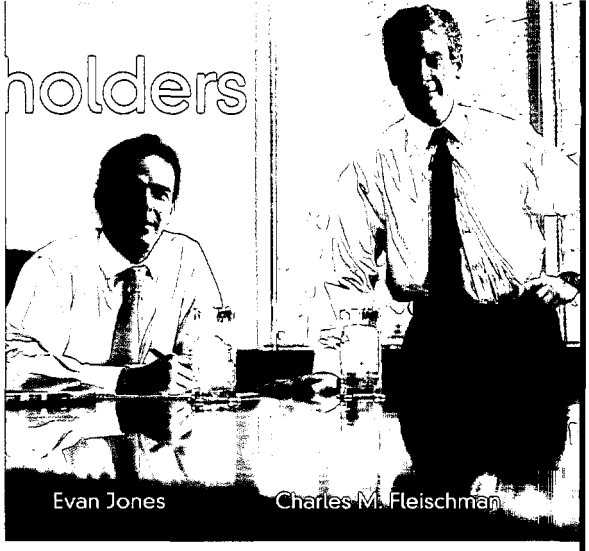
[1] For all our diagnostic test products.



[2] Includes recognition of $14.9 million deferred tax benefit.

Revenue for our HPV DNA test products increased 46%, and we reported record profits during fiscal year 2004. We have achieved 40% compounded annual revenue growth since 1998. With cash and short-term investments of $49 million and profitable operations, we are in a strong financial position.

To Our Stockholders



Fiscal 2004 was a year of record results and significant accomplishments: we successfully launched the DNAwithPap™ Test and reported a 46% increase in HPV test revenues, we received FDA approval for the Rapid Capture® System, and we completed our first full year of profitable operations. Based on the successful execution of our business plan and the growing acceptance of our new DNAwithPap Test, Digene has transformed from a successful molecular diagnostic company to a world-class cervical cancer screening company. Through our pioneering efforts to develop the global market for HPV testing, we are making a significant difference in the fight to eliminate cervical cancer. Our efforts are recognized through the millions of HPV tests now performed on a worldwide basis, and we take great satisfaction in improving the quality of life for the women benefiting from our tests.

Success in the HPV testing market during the year translated into 43% overall revenue growth for the fiscal year to over $90 million. In addition, we achieved essential commercial, regulatory and financial milestones to permit future growth. We are especially pleased to have completed, in fiscal 2004, the majority of our five-point commercialization plan for the DNAwithPap Test ahead of schedule. We also made significant progress developing Digene's worldwide commercial infrastructure, achieved planned financial objectives and prepared for the future of the company.

U.S. Commercial Success Leads Company

The successful launch of the DNAwithPap Test resulted in 9% overall market penetration of the U.S. HPV testing market, which we estimate at 35 million annual tests. This success was largely due to:

- PRACTICE GUIDELINES. During fiscal 2004, cervical cancer screening guidelines incorporating adjunctive screening with an United States Food and Drug Administration (FDA) approved high-risk HPV test were issued by the American College of Obstetricians and Gynecologists, the American Cancer Society and the Association of Reproductive Health Professionals.
- REIMBURSEMENT. Health insurance companies and third-party payors in the United States representing over 175 million covered lives set reimbursement guidelines for adjunctive HPV screening, and payment coverage decisions were issued by some of the nation's largest payors, including Aetna, Anthem, CIGNA, Kaiser Permanente Northern California and UnitedHealthcare.
- LABORATORIES. We signed supply agreements with Quest Diagnostics and Laboratory Corporation of America® Holdings (LabCorp®), two of the largest reference laboratories in the United States as part of our initiative to partner with reference labs to reach and educate physicians on the benefits of our DNAwithPap Test. In total, more than 300 labs in the United States offer Digene's HPV test.

"We had a very successful 2004 fiscal year. Driven by an annual increase in worldwide HPV test revenue of 46% to $74.5 million, we increased total revenues for fiscal 2004 to $90.2 million, and we increased our income before income taxes to $7.2 million. Taking into account the recognition of our deferred tax benefit of $14.9 million, we had net income of $21.5 million or $1.04 per diluted share."

- PHYSICIAN ADOPTION AND EDUCATION. During fiscal 2004, Kaiser Permanente Northern California and Women's Health Connecticut, the nation's largest physician group dedicated to women's health, standardized cervical cancer screening of women age 30 and older on the DNAwithPap Test. These organizations are leaders in helping to establish the standard of care in the United States. In addition, we launched our direct physician education program during the fiscal year.

We are encouraged by our growing success in the United States, and with much of the critical commercialization activities completed for the DNAwithPap Test, we believe we are well positioned to increase our HPV testing market penetration and deliver the top-line growth we expect during fiscal 2005.

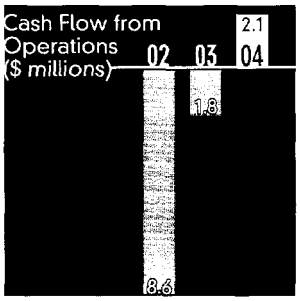
Growing International Success

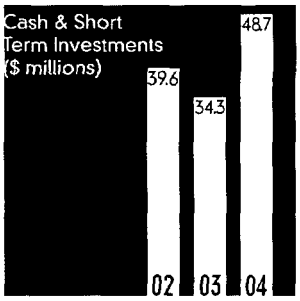
We continue to make progress in increasing the market penetration of our HPV tests in cervical cancer screening programs throughout Europe, Latin and South America and the Asia-Pacific region. We are encouraged by the financial results of our business in Europe. Total revenues increased 42% to approximately $16 million, and HPV test revenue increased 57% to over $12 million. The French Ministry of Health approved reimbursement of testing for high-risk types of HPV in the follow-up evaluation of women with borderline Pap test results—leading to expanded commercial success in France during the year. We are also making good progress with our Latin American and Asian businesses. Total revenues from these regions increased 27% to more than $7 million, and HPV test revenue increased by 31% relative to the prior year to approximately $4 million.

Investing for the Future

As we continue to expand our existing business, we also keep an eye on the future. One of our key goals is to continually expand our core technology and expertise in molecular diagnostics in order to remain at the forefront of DNA testing for women's cancers and infectious diseases. Our research and development investments continue to be directed at productivity improvements for HPV testing, new indications for our technology and associated regulatory approvals, and core research for our next-generation technology. We made excellent progress in the fiscal year on our hc_2 robustness initiative—a multimillion-dollar program focused on scale-up and quality advancements for our HPV, chlamydia and gonorrhea tests. This effort contributed to an excellent quality record during the year. We submitted 510(k)s for chlamydia and gonorrhea testing from ThinPrep® specimens, and we completed work leading to the filing of a PMA supplement for use of the TriPath SurePath™ specimen with our HPV test in August 2004. We completed the initial phases of development for an improved method of processing liquid cytology specimens—we expect to begin clinical trials for regulatory purposes later this year. The new methodology allows for approximately a 50% improvement in specimen processing efficiency. Finally, in 2004, we began work on development of an HPV test for the developing world in conjunction with PATH, the Program for Appropriate Technology in Health.

During the year, we achieved several important regulatory milestones. In May 2004, the FDA approved Digene's Rapid Capture System for high-throughput testing with our hc_2 High-Risk HPV DNA Test™. The system is also cleared for high-throughput testing with our hc_2 Chlamydia and Gonorrhea Tests.





Contributing to the success of our European business, we received CE marking in the European Union under the In Vitro Diagnostics Directive for our hc_2 women's health tests before the required compliance deadline in December 2003. As we look to fiscal 2005, we expect to build on our regulatory and research successes while expanding our efforts to broaden our women's health product offerings.

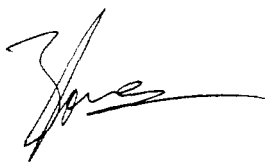
Achieving Financial Success

We had a very successful 2004 fiscal year. Driven by an annual increase in worldwide HPV test revenue of 46% to $74.5 million, we increased total revenues for fiscal 2004 to $90.2 million, and we increased our income before income taxes to $7.2 million. Taking into account the recognition of our deferred tax benefit of $14.9 million, we had net income of $21.5 million or $1.04 per diluted share. We achieved positive cash flow from operations for the first time in fiscal 2004, and we completed the year with approximately $49 million in cash, cash equivalents and short-term investments. Looking to the future, we anticipate continued growth in our core HPV testing business, which should provide the financial resources to further strengthen our global operations and to invest in new initiatives for in-licensing new technologies and products and acquiring businesses or technologies that fit with Digene's core strengths and which can help accelerate the overall development of the company.

Digene has a strong balance sheet, and we have developed into a premier cervical cancer screening company committed to excellence in research and development, manufacturing, sales and marketing, and related disciplines. We now have approximately 400 professionals worldwide. Our global sales and marketing team is approaching 150 professionals, and we have established strong direct sales operations in the United States and Europe. Collectively, these capabilities provide Digene with a unique commercial platform and opportunity to develop, manufacture and market new women's health diagnostic products.

Digene's record of success and accomplishment is gaining increased recognition in the industry and among our peers. During fiscal 2004, the prestigious High Technology Council of Maryland recognized Digene as their High Tech Firm of the Year, and the company was added to the NASDAQ Biotech Index.

The Digene team is energized by our growing list of achievements and the opportunities for the company to help improve the quality of women's lives through better diagnostic testing. We are grateful to our customers, clinical partners and stockholders for their support. During fiscal 2005, we look forward to continuing to develop Digene's position as a leader in women's health diagnostic testing and as an innovator in the molecular diagnostic business.



Evan Jones
Chief Executive Officer and
Chairman of the Board of Directors

Charles M. Fleischman
President, Chief Operating Officer,
Chief Financial Officer and Director

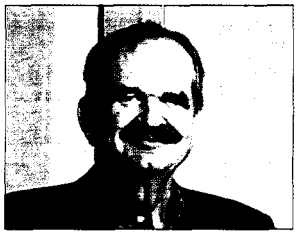
September 9, 2004

Board of Directors


Evan Jones


Charles M. Fleischman


Joseph M. Migliara


John H. Landon


John J. Whitehead


Cynthia L. Sullivan


Kenneth R. Weisshaar

Evan Jones
Chief Executive Officer and Chairman of the Board of Directors, Digene Corporation

Charles M. Fleischman
President, Chief Operating Officer and Chief Financial Officer, Digene Corporation

Joseph M. Migliara
Private Investor

John H. Landon
Retired Executive with E.I. duPont de Nemours and Company

John J. Whitehead
Partner, Whitehead Partners

Cynthia L. Sullivan
President and Chief Executive Officer, Immunomedics, Inc.

Kenneth R. Weisshaar
Former Executive with Becton, Dickinson & Company

Officers


Standing (left to right): Donna Marie Seyfried, Robert McG. Lilley, Charles M. Fleischman, Belinda O. Patrick and Joseph P. Slattery
Seated (left to right): Attila T. Lorincz, Ph.D. and Evan Jones

Evan Jones
Chief Executive Officer and Chairman of the Board of Directors

Charles M. Fleischman
President, Chief Operating Officer and Chief Financial Officer

Robert McG. Lilley
Senior Vice President, Global Sales and Marketing

Attila T. Lorincz, Ph.D.
Senior Vice President, Research and Development and Chief Scientific Officer

Belinda O. Patrick
Senior Vice President, Manufacturing Operations

Joseph P. Slattery
Senior Vice President, Finance and Information Systems

Donna Marie Seyfried
Vice President, Business Development

Digene Corporation 2004 Financials

Company Profile

Digene Corporation develops, manufactures and markets proprietary DNA and RNA testing systems for the screening, monitoring and diagnosis of human diseases. Digene's primary focus is in women's cancers and infectious diseases where the Company's lead product is the only FDA-approved test for human papillomavirus, or HPV, which studies show is the cause of greater than 99% of cervical cancer cases. The Digene hc2 High-Risk HPV DNA Test is approved in the United States for use in conjunction with the Pap test as a primary screen for cervical cancer and its precursors in women age 30 and older and as a follow-up to an abnormal Pap test result in women independent of age. The Company's product portfolio also includes DNA tests for the detection of other sexually transmitted infections, including chlamydia and gonorrhea, and tests for blood viruses.

Significant Product Revenues and Assets

	Fiscal 2002	%	Fiscal 2003	%	Fiscal 2004	%
Product revenues from U.S. operations	$30,070	66%	$45,603	73%	$65,655	74%
Product revenues from non-U.S. operations	$15,680	34%	$16,837	27%	$23,160	26%
Revenues from HPV test products worldwide	$34,034	80%	$51,114	82%	$74,581	84%
Assets located in U.S.	$61,921	92%	$50,843	80%	$92,506	90%
Assets located in outside U.S.	$ 5,320	8%	$12,532	20%	$10,764	10%

Selected Consolidated Financial Data

The selected consolidated financial data set forth below with respect to Digene's Consolidated Statements of Operations for the fiscal years ended June 30, 2002, 2003 and 2004 and with respect to Digene's Consolidated Balance Sheets at June 30, 2003 and 2004 are derived from the audited Consolidated Financial Statements of Digene, which are included elsewhere in this Annual Report. Consolidated Statements of Operations data for the fiscal years ended June 30, 2000 and 2001 and Consolidated Balance Sheet data at June 30, 2000, 2001 and 2002 are derived from Consolidated Financial Statements of Digene not included herein. The selected consolidated financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the Consolidated Financial Statements, the related Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report.

	Fiscal Year Ended June 30,				
	2000	2001	2002	2003	2004
	(in thousands, except per share income (loss))				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales[1]	$22,287	$32,706	$45,750	$62,440	$ 88,815
Distribution contract[1]	—	838	2,357	—	—
Other revenues	757	653	741	662	1,346
Total revenues	23,044	34,197	48,848	63,102	90,161
Costs and expenses:					
Cost of product sales[1]	7,919	12,553	12,938	13,383	16,717
Research and development	6,123	8,120	9,265	10,262	10,744
Selling and marketing[1]	10,652	12,548	19,835	27,913	36,623
General and administrative	6,346	8,336	14,024	16,642	19,298
Abbott termination fee	—	—	2,500	—	—
Amortization of intangible assets	150	150	150	—	—
Total costs and expenses	31,190	41,707	58,712	68,200	83,382
Income (loss) from operations	(8,146)	(7,510)	(9,864)	(5,098)	6,779
Interest income	1,050	1,194	729	593	459
Interest expense	—	(11)	(32)	(273)	(184)
Other income (expense)	513	(37)	(20)	678	163
Income (loss) from operations before income taxes	(6,583)	(6,364)	(9,187)	(4,100)	7,217
Provision for (benefit from) income taxes	184	117	210	224	(14,325)
Net income (loss)	$(6,767)	$ (6,481)	$(9,397)	$(4,324)	$ 21,542[3]
Basic net income (loss) per share[2]	$ (0.44)	$ (0.39)	$ (0.54)	$ (0.24)	$ 1.13
Diluted net income (loss) per share[2]	$ (0.44)	$ (0.39)	$ (0.54)	$ (0.24)	$ 1.04
Basic weighted average shares outstanding[2]	15,296	16,557	17,361	18,136	19,144
Diluted weighted average shares outstanding[2]	15,296	16,557	17,361	18,136	20,806

	June 30,				
	2000	2001	2002	2003	2004
Consolidated Balance Sheet Data:					
Working capital	$ 24,268	$ 26,905	$ 39,828	$ 36,119	$ 61,786
Total assets	35,785	48,195	67,241	63,375	103,270
Long-term debt, less current maturities	—	1,000	3,690	2,154	686
Accumulated deficit	(55,487)	(61,968)	(71,365)	(75,688)	(54,146)
Total stockholders' equity	29,425	26,334	39,639	43,006	86,063

(1) Certain amounts have been reclassified to conform to current presentation.
(2) Computed on the basis described in Note 2 of Notes to Consolidated Financial Statements.
(3) A portion of the increase in net income primarily relates to the partial reversal of the deferred tax valuation allowance approximating $14.9 million.

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our Consolidated Financial Statements and the related Notes to such Consolidated Financial Statements also included in this Annual Report. Some of the information that follows are not statements of historical fact but merely reflect our intent, belief or expectations regarding the anticipated effect of events, circumstances and trends. Such statements should be considered as forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations. Factors that might cause or contribute to differences between our expectations and actual results include: uncertainty of market acceptance of our products by the worldwide medical community; risk that other companies may develop and market tests for human papillomavirus competitive with our own; uncertainty regarding patents and propriety rights in connection with our products and products in development; uncertainty as to ongoing litigation; our need to obtain third-party reimbursement approval from government entities, managed care organizations, and private insurance plans; our ability to scale up our manufacturing to the extent demand for our products increases; our limited sales and marketing experience; the extent of future expenditures for sales and marketing programs; delay in or failure to obtain regulatory approvals for our products in development; uncertainty of clinical trial results for our products in development; uncertainty of future profitability and cash generation from operations; our ability, if necessary, to obtain requisite additional financing to fund our operations beyond calendar year 2005; risks inherent in international transactions, including those relating to our expansion in Europe and elsewhere; and other factors as set forth in our filings with the United States Securities and Exchange Commission.

Overview

Since our incorporation in 1987, we have devoted substantially all of our resources to developing, manufacturing and marketing our proprietary gene-based testing systems using our patented Hybrid Capture technology for the screening, monitoring and diagnosis of human diseases. We have been profitable since the fourth quarter of fiscal 2003; however, from our inception until that time, we incurred substantial operating losses, resulting principally from expenses associated with our research and development programs, including preclinical studies, clinical trials and regulatory submissions for our products, the expansion of our manufacturing facilities and our global sales and marketing activities.

Our revenues, to a significant extent, have been derived from the sales of our diagnostic tests for the presence of human papillomavirus (HPV), which, for fiscal 2004, accounted for 83% of total revenues. We expect that the growing acceptance of HPV testing in cervical cancer screening programs, both in the United States and internationally, will continue to drive the growth in revenues from our HPV test products in the future. In fiscal 2004, our gross margins on product sales increased to 81% as compared to 79% in fiscal 2003. In fiscal 2005, we believe that we will be able to sustain gross margins consistent with fiscal 2004.

We believe that continuing to increase the investments we make in our sales and marketing and in research and development activities is essential to allow us to capitalize more fully on the potential of our HPV test products and our core technology. During fiscal 2004 one significant area of investment was in our European infrastructure and distribution operations, and we expect to continue such investment in fiscal 2005. We are also expanding our sales organization in the United States. We have increased our expenditures in the development of our next-generation Hybrid Capture platforms and other research and development programs related to HPV testing in fiscal 2004 as compared to fiscal 2003 and expect to continue to increase such expenditures in fiscal 2005.

Our sales and marketing expenditures have been and will continue to be focused on accelerating the adoption of HPV testing worldwide. We intend to capitalize on the expanded indications for use of our HPV test products and the growing acceptance of our HPV test products in the United States and internationally by physicians, laboratories and health insurance providers by materially increasing expenditures for sales and marketing programs over the next several quarters. This increase in expenditures will be primarily directed at our markets in the United States and Europe.

We expect our general and administrative expenses will increase to provide adequate infrastructure to support greater sales and marketing activities and more focused research and development activities, to pay the anticipated costs associated with our ongoing litigation matters and to support the overall growth of our business.

Although we anticipate increasing our expenditures as described above, we anticipate that factors such as the impact of our ability to sustain our gross margins will offset the impact such increased expenditures would have on our operating profits. We expect the operating profits which we experienced for the first time at the end of fiscal 2003 and continued throughout fiscal 2004 will continue through fiscal 2005. There can be no assurance that we will meet this goal.

Results of Operations

	Fiscal 2004	% change	Fiscal 2003	% change	Fiscal 2002
	($ in thousands)				
Product sales	$88,815	42%	$62,440	36%	$45,750
HPV test product revenue	74,581	46%	51,114	50%	34,034
Cost of product sales	16,717	25%	13,383	3%	12,938
Gross margin	81%	—	79%	—	72%

COMPARISON OF FISCAL YEAR ENDED JUNE 30, 2004 TO FISCAL YEAR ENDED JUNE 30, 2003

Product sales increased 42% as compared to fiscal 2003. The increase was due primarily to a 46% growth in sales of our HPV test products to approximately $74,581,000, and an increase in equipment sales of 129%, to approximately $5,432,000, as compared to approximately $2,371,000 in fiscal 2003. The majority of the growth in our HPV test product revenue was in the United States, which increased 45% to approximately $57,802,000, and in Europe, which increased 57%, to approximately $12,865,000. In the United States, most of the growth in our HPV test product sales related to the commercial launch of our DNAwithPap™ Test for adjunctive cervical cancer screening with a Pap test for women age 30 and older, an indication approved by the U.S. Food and Drug Administration ("FDA") in March 2003. The increase in revenues from equipment sales primarily related to sales of our Rapid Capture® System following the May 2004 FDA approval of the use of such automated system to perform our diagnostic tests. The growth in product sales in Europe related to the success of our subsidiary operating companies and distributor operations benefiting from our coordinated sales and marketing programs, public awareness campaigns and government education efforts.

Other revenues include research and development contract revenues, equipment rental revenues and licensing revenues. Other revenues increased 103% in fiscal 2004 to approximately $1,346,000 from approximately $662,000 in fiscal 2003. The increase was due primarily to an increase of approximately $505,000 in research and development contract revenue.

Cost of product sales in fiscal 2004 increased 25% as compared to fiscal 2003 primarily due to increased product sales volume. Gross margins on product sales increased to 81% in fiscal 2004 from 79% in fiscal 2003. Our gross margins in fiscal 2003 were impacted by costs of approximately $425,000 associated with a voluntary product recall in fiscal 2003; costs of approximately $260,000 due to a fiscal 2003 increase in reserves in anticipation of planned product discontinuations in Europe in December 2003, other changes in our products offerings and charges of approximately $200,000, after insurance proceeds, for a freezer failure in September 2002, which resulted in damaged inventory. The fiscal 2004 gross margin also increased due to approximately $500,000 of manufacturing efficiencies related to production scale-ups, product consolidations and process improvements implemented during fiscal 2004. These increases in gross margin were partially offset by increased sales of equipment, which have lower gross margins than our diagnostic test products.

Research and development expenses increased 5% in fiscal 2004 to approximately $10,744,000 from approximately $10,262,000 in fiscal 2003. The increase in expenditures was due primarily to a 16% increase in personnel costs to approximately $5,044,000 and a 12% increase in laboratory supplies to approximately $1,108,000, partially offset by a decrease in professional services of 26% to approximately $1,914,000. The decrease in professional services was due largely to decreased expenditures in fiscal 2004, as compared to the costs incurred in fiscal 2003, to obtain CE marking for our HPV, chlamydia and gonorrhea diagnostic test products in accordance with the European Union In Vitro Diagnostic Directive, which CE marking was successfully accomplished in December 2003. Our research and development activities focus on our platform technology, including substantial modifications of the design or capabilities of our products and equipment offerings. Because our research and development expenditures tend to benefit multiple product offerings, we do not track and maintain research and development expenses on a per-product or per-disease target basis.

In fiscal 2004, we focused our research and development activities in four areas: (1) core research efforts for next-generation technologies; (2) new product development activities; (3) completion of activities necessary to support regulatory submissions to seek approvals to market our existing products for additional uses and indications in the U.S. and abroad; and (4) modification of the design or capabilities of our product and equipment offerings.

Our core research efforts for next-generation technologies include research programs with the goal of developing improved molecular diagnostic assay systems for the detection of HPV and other targets of interest in the area of women's cancers and infectious diseases, and research on our next generation of Hybrid Capture technology.

Our new product development activities currently focus on the discovery of innovative methods to improve specimen processing procedures and throughput to expand the ability of laboratories to use our diagnostic tests. The activities include procedures for the improved processing of PreservCyt® (Cytyc Corporation) specimens and upgrades of our equipment offerings for high throughput HPV, chlamydia and gonorrhea testing. We are also working to expand HPV testing capabilities to allow testing from additional liquid cytology media, including our proprietary Universal Collection Medium (UCM™), which is expected to allow simultaneous nucleic acid testing, protein analysis and cytological testing of human papillomavirus DNA, chlamydia DNA and gonorrhea DNA, and of other genetic and cellular material from a single patient sample, and the SurePath™ (TriPath Imaging) medium, for which the clinical validation is ongoing. We have also completed development of a software improvement for our Rapid Capture System to permit the simultaneous testing of multiple DNA probes, and to improve the related laboratory processes and procedures. In addition, in November 2003 we entered into a collaborative product development and commercialization agreement with PATH (Program for Appropriate Technology in Health) to develop a rapid batch HPV test product for use in developing countries. Digene and PATH will jointly fund the efforts subject to certain maximum funding obligations, and Digene will perform the product development and commercialization activities. During the second half of fiscal 2004 we completed the establishment of a research team to pursue this program and began active research into a rapid batch HPV test product candidate.

With respect to regulatory submissions in fiscal 2004 we:

- developed and completed the clinical validation of our Rapid Capture System for semi-automated processing of our hc_2 High-Risk HPV DNA Tests. We initially submitted the Pre-Market Approval Supplement to the FDA on November 5, 2003. We

provided follow-up data and information on April 1, 2004 to facilitate completion of the FDA's review. We received this approval on May 4, 2004. We expect this claim will expand existing indications for our hc_2 High-Risk HPV DNA Test to allow high-volume, semi-automated human papillomavirus DNA testing.

- developed and completed the clinical validation of the use of chlamydia (CT) and gonorrhea (GC) testing using our hc_2 CT/GC Tests from Cytyc Corporation's ThinPrep PreservCyt Solution specimens. We submitted 510(k) pre-market notifications for each of our test products for chlamydia and gonorrhea (each test separately plus our combined hc_2 CT/GC Test) between November 2003 and January 2004. The FDA's review of these submissions is ongoing and we continue to work with the FDA during this period to provide the information needed to facilitate completion of its review.

Finally, with respect to modification of the design or capabilities of our diagnostic test products and equipment offerings, in fiscal 2004 we achieved technical feasibility of our next generation platform proprietary DNA test for ultra-sensitive detection of DNA targets in a highly multiplexed modality.

Selling and marketing expenses increased 31% in fiscal 2004 to approximately $36,623,000 from approximately $27,913,000 in fiscal 2003. The increase in fiscal 2004 was due primarily to personnel costs, which increased 39% to approximately $12,350,000; agency fees, which increased 131% to approximately $5,458,000; professional services, which increased 38% to approximately $2,982,000; and expenses related to the development of physician conferences and education, which increased 922% to approximately $592,000. These increases were partially offset by a decrease in royalties expense, which decreased 39% to approximately $1,705,000, due primarily to the reversal of an accrual of approximately $535,000 based on the reduced probability that a specific royalty liability would materialize. The increase in personnel costs relates to our increased hiring activities. The increase in agency fees relates to costs under our physician detailing agreement with PDI, Inc. PDI recruits and administers a Digene-specific physician detailing sales organization dedicated to educating physicians about the benefits of the DNAwithPap Test in the United States. The professional services increase is due largely to the use of consultants to assist with the rapid growth of our distribution infrastructure in Europe.

Geographically, the majority of the increase in our selling and marketing expenses for fiscal 2004, excluding royalties, was incurred in the United States, which increased 57% to approximately $22,051,000 as compared to approximately $14,032,000 in fiscal 2003, as we expanded our direct sales and marketing activities in the United States to increase sales of our HPV test products.

We expect our selling and marketing expenses to increase during fiscal 2005 as we continue to expand our direct sales and marketing activities to increase HPV test product sales, continue the build-up of our direct sales and marketing operations in Europe and commercialize our CT/GC products. As part of our commercialization program for the DNAwithPap Test, we have extended our contract with PDI, Inc., dedicated to promoting the DNAwithPap Test to physicians. We expect to continue to increase our investment in physician education to promote the commercialization of the DNAwithPap Test.

General and administrative expenses increased 16% in fiscal 2004 to approximately $19,298,000 from approximately $16,642,000 in fiscal 2003. The increase was due primarily to personnel costs, which increased 19% to approximately $7,832,000; insurance, which increased 44% to approximately $1,373,000, principally related to increased costs for directors' and officers' insurance coverage; and professional fees, which increased 6% to approximately $7,664,000, primarily related to costs associated with legal matters, which increased 18% to approximately $6,057,000.

Geographically, the majority of the increase in general and administrative expenses for fiscal 2004 was incurred in Europe, which increased 126%, to approximately $5,561,000, over the corresponding period in fiscal 2003 as we invested in infrastructure required to support the direct distribution of our products in Europe.

Interest income decreased 23% to approximately $459,000 in fiscal 2004 from approximately $593,000 in fiscal 2003. The decrease was due to lower interest rates in fiscal 2004 compared to the corresponding period in fiscal 2003.

Interest expense decreased to approximately $184,000 in fiscal 2004 compared to approximately $273,000 in fiscal 2003 primarily due to the reduction in our long-term debt due to Abbott Laboratories as quarterly principal payments were made on an outstanding promissory note, which lowered the debt.

Other income decreased to approximately $163,000 in fiscal 2004 compared to $678,000 in fiscal 2003, due almost entirely to reduced foreign exchange gains as exchange rate fluctuations were not as significant in fiscal 2004 as they were in 2003.

The net income tax benefit of approximately $14,325,000 in fiscal 2004 is primarily related to the partial release of the valuation allowance previously established against our deferred tax assets. We released approximately $14,900,000 of valuation reserve in the fourth quarter of fiscal 2004. Based upon projected future operating performances, we currently believe that we will be able to utilize a portion of the value of our net operating loss carryforward (NOL) through the reduction of future taxable income. During fiscal 2004, the amount of valuation allowance we released was the estimated amount to be utilized in the foreseeable future. As of June 30, 2004, we had total NOL carryforwards of approximately $115 million; however, we did not reverse the portion of the valuation allowance related to the potential tax benefits from the exercise of stock options as realization of these benefits are not likely at this time. Should realization of these benefits become more likely than not, the benefit will be reflected as a reclassification to stockholders' equity.

COMPARISON OF FISCAL YEAR ENDED JUNE 30, 2003 TO FISCAL YEAR ENDED JUNE 30, 2002

Product sales in fiscal 2003 increased 36% as compared to fiscal 2002. The increase was due primarily to a 40% growth in sales of our HPV test products to approximately $51,114,000, partially offset by a decrease in sales of equipment and certain non-core products

of approximately $1,691,000 (32%). The majority of the growth in HPV product sales was in the United States (64% over such sales in fiscal 2002) and in Europe (30% over such sales in fiscal 2002).

During fiscal 2003, we did not recognize any revenue related to minimum purchase guarantees under the Roche Distribution Contract, whereas in fiscal 2002 we recognized approximately $2,357,000. Please see "Liquidity and Capital Resources" below for a description of the Roche Distribution Contract.

Other revenues included research and development contract revenues, equipment rental revenues and licensing revenues. Other revenues decreased almost 11% in fiscal 2003 to approximately $662,000 from approximately $741,000 in fiscal 2002. The decrease was due primarily to reductions in research and development services revenue of approximately $279,000 (82%) and licensing revenue of approximately $84,000 (95%). The decrease was partially offset by the recognition of $288,000 of certain equipment sales to Roche in Europe, which were initially deferred in the fourth quarter of fiscal 2002. Please see "Liquidity and Capital Resources" below for a description of the Roche Distribution Contract.

Cost of product sales in fiscal 2003 increased 3% as compared to fiscal 2002. Gross margins on product sales increased to 79% in fiscal 2003 from 72% in fiscal 2002. The increase in gross margin percentage primarily related to increased sales of our higher margin reagent test kits, particularly HPV tests products, which represented 81%, or approximately $51,114,000, of product revenue in fiscal 2003 compared to 75%, or approximately $34,034,000, in fiscal 2002, principally in the United States, as well as decreased sales of lower margin equipment products that represented 4%, or approximately $2,401,000, of product revenue in fiscal 2003 compared to 8%, or approximately $4,050,000, in fiscal 2002.

Cost of product sales was negatively impacted in fiscal 2003 because of a voluntary product recall, resulting in a charge to Cost of product sales of approximately $425,000 during February 2003. We initiated a voluntary recall involving our hc_2 HPV and chlamydia test products. This recall was limited to certain product lots which were manufactured using a specific lot of raw material that had the potential to cause false positive patient specimen results. We informed the FDA of the recall. We conducted an investigation into the root cause of this product performance issue for our Hybrid Capture 2 product line, and developed a raw material release testing corrective action plan. On June 20, 2003, the FDA approved the modification of our lot release testing procedures related to the component that relied on the raw material found to have been contaminated. Because this voluntary recall was limited to an identified lot of raw material, we were able to supply our customers with product manufactured from acceptable raw material lots. In addition, we expanded our ongoing quality improvement program to ensure continued reliability as manufacturing volume increases to meet anticipated growth in demand for our diagnostic test products.

Research and development expenses increased 11% in fiscal 2003 to approximately $10,262,000 from approximately $9,265,000 in fiscal 2002. The increase in expenses was due primarily to a 305% increase in professional services and clinical trial expenses, to approximately $2,593,000, partially offset by a decrease in personnel costs, which decreased 11% to approximately $4,364,000, and laboratory supplies, which decreased 29% to approximately $815,000. The increase in professional services was due largely to costs incurred of approximately $1,051,000, in preparation for compliance with the CE marking requirements of the European Union In Vitro Diagnostic Directive. Our research and development activities focus on our platform technology, including different or modified uses of such technology, and improvements to our diagnostic test and equipment products. Because our research and development expenditures tend to benefit multiple product offerings, we do not track and maintain research and development expenses on a per-product or per-disease target basis.

During fiscal 2003, we focused our research and development activities on completing regulatory activities to add new claims and indications to existing products in the U.S. and abroad, support and improvement of existing product lines, the development of several new products and core research efforts for next-generation technologies. Work continued on the development of a Hybrid Capture HPV test product application for our automated Rapid Capture System, including accommodating the use of multiple DNA probes in a single run in conjunction with our current product lines; the development of methods to improve specimen processing procedures and throughput, including procedures for the improved processing of Cytyc Corporation's ThinPrep specimens for HPV, chlamydia and gonorrhea testing; improved equipment for faster specimen processing; and the development of our Universal Collection Medium. In addition, verification was completed and clinical trials initiated for a method for converting specimens collected in TriPath Imaging's SurePath liquid cytology medium; clinical trials occurred to validate chlamydia and gonorrhea testing from Cytyc Corporation's ThinPrep specimens, a human papillomavirus application for our Rapid Capture System, and a procedural modification to our hc_2 assay designed to improve test robustness. Work was completed on an HPV ThinPrep application using cervical specimens collected with a brush/spatula device and the data were submitted to the FDA.

Selling and marketing expenses increased 41% in fiscal 2003 to approximately $27,913,000 from approximately $19,835,000 in fiscal 2002. The increase in fiscal 2003 was due primarily to personnel costs, which increased 44% to approximately $8,776,000, and royalty expenses, which increased 34% to approximately $2,814,000. In addition, depreciation expense increased 140% to approximately $2,359,000 in fiscal 2003, due primarily to the May 2002 repurchase of equipment from Abbott Laboratories upon expiration of the non-exclusive wind-down period of our distribution agreement with Abbott. Additionally, professional services increased 79% to approximately $2,160,000, due largely to the use of consultants to assist with the rapid growth of our distribution infrastructure in Europe.

Geographically, the majority of the increase in our selling and marketing expenses for fiscal 2003, excluding royalties, was incurred in Europe, which increased 79% to approximately $9,867,000 over the corresponding period in fiscal 2002 as we established subsidiaries, hired employees and continued to develop a distribution infrastructure.

General and administrative expenses increased 19% in fiscal 2003 to approximately $16,642,000 from approximately $14,024,000 in fiscal 2002. The increase was due primarily to professional fees, which increased 26% to approximately $7,222,000, primarily related to costs associated with legal matters, which increased 42% to approximately $4,689,000; personnel costs, which increased 34% to approximately $6,577,000; and insurance, which increased 84% to approximately $952,000, principally related to increased costs for directors' and officers' insurance coverage. These increases were partially offset by a decrease in bad debt expense of $526,000 during fiscal 2003 due to strong collection efforts of outstanding receivables.

Geographically, the majority of the increase in general and administrative expenses for fiscal 2003 was incurred in Europe, which increased 618% to approximately $2,461,000 over the corresponding period in fiscal 2002 due to our change to direct distribution, and in the United States, which increased 4% over the corresponding period in fiscal 2002 to approximately $13,869,000, due primarily to the aforementioned litigation expenditures.

Interest income decreased 19% in fiscal 2003 to approximately $593,000 from approximately $729,000 in fiscal 2002. The decrease was primarily due to a decrease in average cash balances and lower interest rates in fiscal 2003 compared to the corresponding period in fiscal 2002.

Interest expense increased to approximately $273,000 in fiscal 2003 compared to approximately $32,000 in fiscal 2002 due to interest on long-term debt due to Abbott Laboratories as part of the repurchase of equipment at the end of fiscal 2002 under a terminated distribution agreement, and interest on a promissory note due to Roche Molecular Diagnostics as a result of the repurchase of inventory from Roche in January 2003.

Other income increased to approximately $678,000 in fiscal 2003 from a loss of approximately $20,000 in fiscal 2002 primarily due to foreign exchange gains and losses.

Liquidity and Capital Resources

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of approximately $54,146,000 at June 30, 2004. We have funded our operations primarily through the sale of equity securities and revenues from product sales and research and development contracts. At June 30, 2004, we had cash, cash equivalents and short-term investments aggregating approximately $48,733,000. We had positive cash flows from operations of approximately $2,064,000 for the year ended June 30, 2004 compared to negative cash flows from operations of approximately $1,834,000 for the year ended June 30, 2003. The increase in cash provided from operations was due primarily to net income for fiscal 2004 of approximately $21,542,000, which included a deferred tax benefit of $14,899,000, compared to a net loss of approximately $4,324,000 for fiscal 2003, partially offset by an increase of approximately $7,201,000 in the cash used for net accounts receivable due to increased sales in fiscal 2004.

Net cash used in investing activities for fiscal 2004 included approximately $6,139,000 of capital expenditures. This included approximately $2,829,000 of equipment placed at customer sites, which allows our customers to run diagnostic tests using our reagent test kit products, and approximately $1,804,000 of leasehold improvements, primarily at our headquarters facility in Gaithersburg, Maryland. In fiscal 2005 we expect both of these types of capital expenditures to be significant uses of working capital as we continue to place equipment at customer sites, specifically Rapid Capture Systems, and as we further expand our warehouse capacity at our Gaithersburg facility, for which we may obtain alternative financing.

On April 29, 2001, we entered into a letter agreement with Roche Molecular Systems (the "Roche Distribution Contract"), which established Roche Molecular Systems ("Roche") as the coexclusive distributor of our human papillomavirus ("HPV") products in Europe, Africa and the Middle East from May 1, 2001 through June 30, 2002. In June 2002, we adopted as our sole strategy for the distribution of our HPV products in Europe, Africa and the Middle East, a combination of direct distribution through our European infrastructure and the use of local distributors and agents.

On June 30, 2002, the term of the Roche Distribution Contract expired, subject to a nonexclusive wind-down period. Under the Roche Distribution Contract, we had the option, exercisable within 30 days after December 31, 2002, to buy back from Roche equipment purchased from us by Roche and in use for HPV testing in customer's laboratories on June 30, 2002. In June 2002, as part of our strategic decision, we decided that we would exercise the option to repurchase the equipment.

In recognition of the decision to repurchase the equipment, commencing in the fourth quarter of 2002, we deferred recognition of equipment sold to Roche. Equipment sold during this time period had a sales price of $2.3 million and a cost of $1.4 million, which amounts were recorded as deferred revenue and deferred costs, respectively. The deferred revenue and deferred costs were being amortized over a four-year period to other revenue (as equipment rental) and selling and marketing expenses, respectively. For fiscal 2002, we recorded other revenue and selling and marketing expenses of $109,000 and $67,000, respectively, related to the amortization of these balances. For fiscal 2003, we recorded other revenue and selling and marketing expenses of $288,000 and $177,000, respectively, related to the amortization of these balances prior to the commencement of the repurchase. At December 31, 2002, when amortization ceased, the remaining deferred revenue and deferred cost balances were $1,904,000 and $1,169,000, respectively, for a remaining net credit as of December 31, 2002 of $734,000.

On December 20, 2002, we amended the Roche Distribution Contract to terminate the wind-down period on December 31, 2002 and to establish the procedures for our repurchase from Roche of HPV-related testing equipment purchased from us by Roche under the Roche Distribution Contract. The repurchase price for the equipment in use for HPV testing in customers' laboratories is the equipments' December 31, 2002 depreciated value, which is the net selling price less any amounts Roche recorded as depreciation based on a straight-line basis over a four-year period. The repurchase price for the equipment in inventory is a discount from the transfer price paid by Roche under the Roche Distribution Contract.

The parties consummated the HPV equipment repurchase on January 6, 2003, subject to reconciliation. In January 2003 Digene and its affiliates paid Roche an aggregate of approximately $2.6 million for the HPV equipment in inventory and in use at customers' laboratories in Europe. A portion of the purchase price was paid by the issuance of a note payable due to Roche, which was paid in one installment in January 2004, and the remainder of the purchase price was paid in cash. A final settlement for the repurchased assets was completed with Roche in June 2003.

The total consideration paid to Roche for the fixed assets and inventory after reaching a final settlement was $2,488,000, or $1,753,000 after consideration of the remaining net credit of $734,000 mentioned above.

We anticipate that working capital requirements will increase moderately for the foreseeable future due to the investment necessary to support our European direct distribution operations, as well as increasing accounts receivable as a result of expected revenue growth. Prior to this fiscal year, we had incurred negative cash flows from operations since our inception. We have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts, expand our sales and marketing activities and expand our manufacturing capabilities. We expect that our existing capital resources will be adequate to fund our operations through calendar 2005. Our future capital requirements and the adequacy of available funds may change, however, based on numerous factors, including our degree of success in commercializing our products; our progress in product development efforts and the magnitude and scope of such efforts; our success in increasing and maintaining customer relationships; our ability to receive additional regulatory approvals for our product offerings; the cost and timing of expansion of our manufacturing capabilities; the effectiveness of our sales and marketing activities; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and competitive market developments. To the extent that our existing capital resources and funds generated from operations are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources. We do not have any committed sources of additional financing, and there can be no assurance that additional funding, if necessary, will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. Under such conditions, our business, financial condition and results of operations will be materially adversely affected.

We have summarized below our material contractual obligations as of June 30, 2004 (in thousands):

CONTRACTUAL OBLIGATIONS	Total	Less than One Year (Fiscal 2005)	One to Three Years (Fiscal 2006–2008)	Four to Five Years (Fiscal 2009–2010)	After Five Years (After Fiscal 2010)
Long-term debt[1]	$ 2,145,830	$ 1,459,890	$ 352,843	$ 333,097	$ —
Physician detailing agreement	5,182,904	5,182,904	—	—	—
Operating leases	17,816,572	3,407,982	9,568,452	4,680,431	159,707
Total contractual cash obligations	$25,145,306	$10,050,776	$9,921,295	$5,013,528	$159,707

(1) Includes debt payable to Abbott Laboratories related to the repurchase of equipment in fiscal 2002.

Critical Accounting Policies and the Use of Estimates

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. Such accounting principles require that our management make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Our actual results could differ materially from those estimates. The items in our consolidated financial statements that have required us to make significant estimates and judgments are as follows:

- *Inventory management.* Our inventories are stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in first-out method of inventory management. We also record provisions for inventories which may not be salable due to anticipated trends in sales volume and/or pricing and our estimates of net realizable value. These provisions are determined based on significant estimates.
- *Revenue recognition.* We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. We establish allowances for estimated uncollectible amounts, product returns and discounts based on historical default rates and specifically identified problem accounts. Additionally, we defer approximately two percent of product sales as a reserve for future warranty costs and recognize this deferred revenue over one year, which is the standard warranty period for a majority of our system components. At June 30, 2003 and 2004, the warranty reserve was approximately $633,000 and $897,000, respectively, and, historically, the warranty costs have been within management estimates.
- *Accounting for employee stock options.* We account for our employee stock-based compensation in accordance with the provisions of APB No. 25, and related interpretations, which allow us to recognize compensation costs for the excess of the fair value of the stock at the grant date over the exercise price, if any. An alternative method of accounting would apply the principles of SFAS No. 123, which require the fair value of the stock option to be recognized at the date of grant and amortized to compensation expense over the stock option's vesting period. Had we applied the principles of SFAS No. 123 for our employee options, our net loss would have been approximately $24,451,000 and $17,381,000 during our fiscal years ended June 30, 2002 and 2003, respectively, and our net income would have been approximately $15,080,000 during our fiscal year ended June 30, 2004, instead of our reported net losses which approximated $9,397,000 and $4,324,000 during our fiscal years ended June 30, 2002 and 2003, respectively, and our reported net income of approximately $21,542,000 during our fiscal year ended June 30, 2004.
- *Income taxes.* We provide for income taxes in accordance with the liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis 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. We recognized an income tax benefit of $14,324,947 for the year ended June 30, 2004, primarily related to the reversal of a portion of the valuation allowance previously established for our deferred tax asset. Realization of total deferred tax assets is contingent upon the generation of future taxable income. Due to the uncertainty of realization of these tax benefits, in fiscal 2004 we have provided a valuation allowance for the portion of the net operating loss carryforward and the research and development credits related to the exercise of stock options and the amount of net operating loss carryforwards and credits expected to expire unused. We review our deferred tax asset on a quarterly basis to determine if a valuation allowance is required, 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 valuation allowance and an expense in the period of change. Substantially all of the remaining deferred tax asset valuation allowance, if released, will be reflected as a direct increase to stockholders' equity and will not impact the consolidated statement of operations.

Quantitative and Qualitative Disclosures About Market Risk

We are subject to market risk associated with changes in foreign currency exchange rates and interest rates. Our exchange rate risk comes from our operations in Europe and South America. The net impact of foreign exchange activities on earnings was immaterial for the years ended June 30, 2002, 2003 and 2004. Interest rate exposure is primarily limited to the $48.7 million of cash, cash equivalents and short- and long-term investments owned by us. Such investments are money market debt securities that generate interest income for us on cash balances. We do not actively manage the risk of interest rate fluctuations; however, such risk is mitigated by the relatively short term nature of our investments. We do not consider the present rate of inflation to have a significant impact on our business.

Consolidated Balance Sheets

	June 30, 2003	June 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,883,129	$ 4,079,519
Short-term investments	26,408,994	44,653,599
Accounts receivable, less allowance of approximately $432,000 and $600,000 at June 30, 2003 and 2004, respectively	10,344,597	17,545,133
Inventories, net	7,073,920	8,109,987
Prepaid expenses and other current assets	2,189,225	2,392,048
Deferred tax asset, current	—	1,047,766
Total current assets	53,899,865	77,828,052
Property and equipment, net	7,515,104	9,561,794
Intangible assets, net	900,515	900,515
Deposits and other assets	1,059,666	1,249,971
Deferred tax asset	—	13,729,916
Total assets	$ 63,375,150	$103,270,248
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,489,700	$ 5,423,628
Accrued expenses	3,467,629	3,771,141
Accrued payroll	4,182,327	5,387,129
Current portion of long-term debt	2,640,363	1,459,890
Total current liabilities	17,780,019	16,041,788
Deferred rent	434,908	479,078
Long-term debt, less current portion	2,154,244	685,940
Stockholders' equity:		
Preferred Stock, $0.10 par value, 1,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock, $0.01 par value, 50,000,000 shares authorized, 18,325,208 and 19,883,918 shares issued and outstanding at June 30, 2003 and 2004, respectively	183,252	198,839
Additional paid-in capital	118,535,272	139,637,245
Deferred stock compensation	(380,633)	(164,031)
Accumulated other comprehensive income	356,415	537,688
Accumulated deficit	(75,688,327)	(54,146,299)
Total stockholders' equity	43,005,979	86,063,442
Total liabilities and stockholders' equity	$ 63,375,150	$103,270,248

See accompanying notes.

Consolidated Statements of Operations

	Year Ended June 30,		
	2002	2003	2004
Revenues:			
Product sales	$45,750,124	$62,440,415	$ 88,815,293
Distribution contract	2,357,239	—	—
Other	740,414	661,481	1,345,275
Total revenues	48,847,777	63,101,896	90,160,568
Costs and expenses:			
Cost of product sales	12,937,556	13,383,086	16,716,387
Research and development	9,264,548	10,262,138	10,743,763
Selling and marketing	19,835,304	27,912,724	36,623,243
General and administrative	14,024,276	16,642,100	19,297,782
Abbott termination fee	2,500,000	—	—
Amortization of intangible assets	150,086	—	—
Total costs and expenses	58,711,770	68,200,048	83,381,175
Income (loss) from operations	(9,863,993)	(5,098,152)	6,779,393
Other income (expense)			
Interest income	729,681	593,331	459,170
Interest expense	(32,217)	(272,810)	(183,945)
Other income (expense)	(19,981)	677,585	162,463
Total other income (expense)	677,483	998,106	437,688
Income (loss) from operations before income taxes	(9,186,510)	(4,100,046)	7,217,081
Provision for (benefit from) income taxes	210,106	223,465	(14,324,947)
Net income (loss)	$ (9,396,616)	$ (4,323,511)	$ 21,542,028
Basic net income (loss) per share	$ (0.54)	$ (0.24)	$ 1.13
Diluted net income (loss) per share	$ (0.54)	$ (0.24)	$ 1.04
Weighted average shares outstanding			
Basic	17,360,725	18,135,689	19,144,021
Diluted	17,360,725	18,135,689	20,806,078

See accompanying notes.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in	Deferred Stock	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Compensation	Income	Deficit	Equity
Balance at June 30, 2001	16,755,339	$167,553	$ 88,199,211	$ (64,274)	$ —	$(61,968,200)	$26,334,290
Exercise of Common Stock options	541,281	5,413	5,244,020	—	—	—	5,249,433
Issuance of Common Stock in connection with private placement financing	588,235	5,882	14,913,658	—	—	—	14,919,540
Issuance of Common Stock in connection with Abbott agreement	87,873	879	2,499,121	—	—	—	2,500,000
Compensatory stock options earned by non-employees	—	—	—	32,137	—	—	32,137
Net loss	—	—	—			(9,396,616)	(9,396,616)
Balance at June 30, 2002	17,972,728	179,727	110,856,010	(32,137)	—	(71,364,816)	39,638,784
Comprehensive loss:							
Foreign currency translation	—	—	—	—	356,415	—	356,415
Net loss		—		—	—	(4,323,511)	(4,323,511)
Comprehensive loss							(3,967,096)
Exercise of Common Stock options	209,623	2,096	2,079,691	—	—	—	2,081,787
Issuance of Common Stock to Roche	142,857	1,429	4,998,571	—	—	—	5,000,000
Issuance of Common Stock options to non-employees	—	—	601,000	(601,000)	—	—	—
Compensatory stock options earned by non-employees	—	—	—	252,504	—	—	252,504
Balance at June 30, 2003	18,325,208	183,252	118,535,272	(380,633)	356,415	(75,688,327)	43,005,979
Comprehensive income:							
Foreign currency translation, net of income tax expense of $173,979	—	—	—	—	260,968	—	260,968
Unrealized loss on available for-sale securities, net of income tax benefit of $53,130	—	—	—	—	(79,695)	—	(79,695)
Net income	—	—	—	—	—	21,542,028	21,542,028
Comprehensive income							21,723,301
Exercise of Common Stock options	1,558,710	15,587	20,882,723	—	—	—	20,898,310
Compensatory stock options earned by non-employees	—	—	219,250	216,602	—	—	435,852
Balance at June 30, 2004	19,883,918	$198,839	$139,637,245	$(164,031)	$537,688	$(54,146,299)	$86,063,442

See accompanying notes.

Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2002	2003	2004
OPERATING ACTIVITIES			
Net income (loss)	$ (9,396,616)	$ (4,323,511)	$ 21,542,028
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Abbott termination fee	2,500,000	—	—
Write-off note receivable	406,500	—	—
Depreciation and amortization of property and equipment	1,769,567	3,293,454	3,914,062
Amortization of intangible assets	150,086	—	—
Amortization of discount on note payable	—	—	35,603
Loss on disposal of fixed assets	—	22,925	178,036
Compensation expense related to stock options	32,137	252,504	435,852
Deferred tax benefit	—	—	(14,898,531)
Changes in operating assets and liabilities:			
Accounts receivable	(3,306,936)	(1,343,013)	(7,200,536)
Inventories	(431,971)	259,177	(1,036,067)
Prepaid expenses and other current assets	(509,497)	6,039	(202,823)
Deferred costs	(1,412,524)	—	—
Deposits and other assets	(110,699)	(233,725)	(190,305)
Accounts payable	3,236,220	993,294	(2,066,072)
Accrued expenses	2,919,216	(2,161,077)	303,512
Accrued payroll	998,659	1,317,891	1,204,802
Deferred revenues	(5,600,431)	—	—
Deferred rent	119,492	81,832	44,170
Net cash provided by (used in) operating activities	(8,636,797)	(1,834,210)	2,063,731
INVESTING ACTIVITIES			
Purchases of short-term investments	(35,755,094)	(29,940,689)	(52,712,116)
Sales of short-term investments	14,592,392	33,671,809	34,334,686
Capital expenditures	(1,542,601)	(3,763,786)	(6,138,788)
Net cash used in investing activities	(22,705,303)	(32,666)	(24,516,218)
FINANCING ACTIVITIES			
Net proceeds from issuance of Common Stock	14,919,540	—	—
Exercise of Common Stock options	5,249,433	2,081,787	20,898,310
Principal payments of long-term debt	—	(1,428,492)	(2,684,380)
Net cash provided by financing activities	20,168,973	653,295	18,213,930
Effect of currency translations	—	(356,415)	434,947
Net decrease in cash and cash equivalents	(11,173,127)	(1,569,996)	(3,803,610)
Cash and cash equivalents at beginning of year	20,626,252	9,453,125	7,883,129
Cash and cash equivalents at end of year	$ 9,453,125	$ 7,883,129	$ 4,079,519
SUPPLEMENTAL CASH FLOW INFORMATION			
Interest paid	$ 13,000	$ 374,000	$ 163,000
Income taxes paid	$ 72,000	$ 149,000	$ 345,000

See accompanying notes.

Notes to Consolidated Financial Statements

1. Organization and Nature of Operations

Digene Corporation (the "Company" or "Digene") was incorporated as a Delaware corporation in 1987. The Company develops, manufactures and markets its proprietary gene-based testing systems for the screening, monitoring and diagnosis of human diseases. The Company has applied its proprietary Hybrid Capture, technology to develop a diagnostic test for human papillomavirus ("HPV"), which is the primary cause of cervical cancer and is found in greater than 99% of all cervical cancer cases. Digene's product portfolio also includes gene-based tests for the detection of chlamydia, gonorrhea, hepatitis B virus ("HBV"), and cytomegalovirus ("CMV").

On June 28, 1996, the Company entered into a joint venture agreement with a Brazilian national to establish Digene do Brasil LTDA, a majority-owned subsidiary of the Company.

In October 1997, the Company established Digene B.V., a Netherlands limited liability company, to act as the Company's European distributor; in 1999 Digene B.V. was made dormant. On March 3, 1998, the Company established a wholly-owned Delaware subsidiary, Digene Europe, Inc., for the marketing of the Company's products in Europe. In 2003 Digene Europe, Inc. became inactive as a result of changes in the Company's distribution plans and assumption of the marketing activities in Europe by the Company's newly-formed European entities. On July 1, 1998, the Company acquired Viropath B.V., a company with limited liability, registered in Amsterdam, The Netherlands. Viropath B.V. was liquidated in 2004 after existing patents were assumed by the Company.

On April 26, 2002, the Company established a wholly-owned subsidiary, Digene UK (Holdings) Limited, to be a holding company for its European subsidiaries. Digene UK (Holdings) Limited owns all the outstanding shares of Digene (UK) Limited, Digene Deutschland GmbH, Digene (France) SAS and Digene Italia s.r.l., which were organized in April, May, August and October 2002, respectively, and of Digene Diagnostics S.L. (Spain), which was organized in June of 2003. In July 2002, the Company also organized Digene (Switzerland) Sarl, all of the outstanding shares of which are owned by Digene. Through these newly formed entities and the use of local distributors and agents, Digene markets and distributes the Company's products throughout Europe.

2. Summary of Significant Accounting Policies

PRINCIPLES OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of Digene and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

USE OF ESTIMATES

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

FOREIGN CURRENCIES

The local currency is the functional currency for most of the Company's international subsidiaries and, as such, assets and liabilities are translated into U.S. dollars at year-end exchange rates. Income and expense items are translated at average exchange rates during the year. Translation adjustments resulting from this process are charged or credited to other comprehensive income (expense). Certain transaction gains and losses on intercompany activity for which settlement is not planned in the foreseeable future are charged to cumulative translation adjustment included in stockholders' equity in accumulated other comprehensive income in the accompanying balance sheets.

SEGMENT INFORMATION

The Company operates one business segment that develops, manufactures and markets proprietary gene-based tests for the detection, screening and monitoring of human diseases. Revenue by geographic location is presented in Note 11.

CASH AND CASH EQUIVALENTS

Cash equivalents, which are stated at cost, consist of highly liquid investments with original maturities of three months or less. Substantially all cash equivalents are held in short-term money market accounts with large high-quality institutions.

SHORT-TERM INVESTMENTS

Short-term investments consist of corporate and various government agency debt securities, most of which mature in approximately one year or less. For investments with maturities over one year, management has the intent and ability to sell these securities for working capital purposes should the need arise. Management classifies the Company's short-term investments as available-for-sale. Such securities are stated at market value, with any material unrealized holding gains or losses reported, net of any tax effects, as accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary, if any, are included in operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in fair value, which is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. Dividend and interest income are recognized when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments in highly rated financial institutions.

TRADE RECEIVABLES

Trade receivables are reported in the consolidated balance sheets at outstanding principal less any charge offs and the allowance for doubtful accounts. The Company charges off uncollectible receivables against the allowance for doubtful accounts when the likelihood of collection is remote. Generally, the Company considers receivables past due 30 days subsequent to the billing date; however, the Company may extend credit terms up to 180 days. The Company performs ongoing credit evaluations of its customers

and generally extends credit without requiring collateral. The Company maintains an allowance for doubtful accounts, which is determined based on historical experience, existing economic conditions and managements' expectations of losses. Losses have historically been within managements' expectations. As of June 30, 2003 and 2004, the Company had an allowance for doubtful accounts of approximately $432,000 and $600,000, respectively.

CONCENTRATION OF CREDIT RISK AND FINANCIAL INSTRUMENTS

The Company places its cash and cash equivalents with financial institutions and its short-term investments consist of U.S. government agency and high-grade corporate debt securities. Management believes that the financial risks associated with its cash and cash equivalents and short-term investments are minimal.

The fair value of the Company's accounts receivable, accounts payable and accrued liabilities approximate their carrying amount due to the relatively short maturity of these items. The fair value of debt approximates its carrying amount as of June 30, 2003 and 2004 based on rates currently available to the Company for debt with similar terms and maturities.

SIGNIFICANT SUPPLIERS

Several key components of the Company's products come from, or are manufactured for the Company by, a single supplier or limited number of suppliers. This applies in particular to three components, chemiluminescent substrates (used to create a chemical reaction that causes light in connection with the Hybrid Capture signal amplified molecular technology), the Rapid Capture System that serves as the automation platform developed for large-scale diagnostic testing using the Hybrid Capture technology and the 96-well microplate used by laboratories to run the Company's diagnostic test products.

INVENTORIES

Inventories are stated at the lower of cost or market on a standard cost basis, which approximates average cost. The estimated reserve is based on management's review of inventories on hand compared to estimated future usage and sales, shelf-life and assumptions about the likelihood of obsolescence.

PROPERTY AND EQUIPMENT

Property and equipment, including leasehold improvements, are stated at cost and depreciated or amortized using the straightline method over the estimated useful lives of three to ten years. Leasehold improvements are amortized over the lesser of the related lease term or the useful life. Repairs and maintenance expenditures are charged to operations as incurred.

INTANGIBLE ASSETS

Intangible assets arose from the Company's acquisition of Viropath B.V. in 1998. The excess of the purchase price over the identifiable tangible net assets acquired of approximately $1.5 million was being amortized on a straight-line basis over ten years until June 2002. On July 1, 2002, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets," which requires that goodwill and intangible assets deemed to have an indefinite useful life be reviewed for impairment upon the adoption of SFAS 142 and annually thereafter. The Company has ceased the amortization of the intangible assets effective July 1, 2002, and instead reviews intangible assets in the fourth quarter of each fiscal year for evidence of impairment, and will adjust the recorded value, if necessary. The Company reviewed the value of the intangible assets in the fourth quarter of fiscal year 2004 and did not note any circumstances which would warrant an adjustment to the recorded value. Accumulated amortization expense approximated $600,000 as of June 30, 2004.

If goodwill and other intangible assets had been accounted for in accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," from the date of acquisition, net income (loss) and EPS would be as follows:

	Year Ended June 30,		
	2002	2003	2004
Net income (loss), as reported	$(9,396,616)	$(4,323,511)	$21,542,028
Amortization expense	150,086	—	—
Pro forma net income (loss)	$(9,246,530)	$(4,323,511)	$21,542,028
Net income (loss) per share			
Basic—as reported	$ (0.54)	$ (0.24)	$ 1.13
Basic—pro forma	$ (0.53)	$ (0.24)	$ 1.13
Diluted—as reported	$ (0.54)	$ (0.24)	$ 1.04
Diluted—pro forma	$ (0.53)	$ (0.24)	$ 1.04

IMPAIRMENT OF LONG-LIVED ASSETS AND RECOVERABILITY OF INTANGIBLES

The Company periodically evaluates the recoverability of the carrying value of its long-lived assets and identifiable intangibles whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Examples of events or changes in circumstances that indicate that the recoverability of the carrying value of the assets should be assessed include, but are not limited to, the following: a significant decrease in the market value of an asset, a significant change in the extent or manner in which an asset is used or a significant physical change in an asset, a significant adverse change in legal factors or in the business climate that could affect the value of an asset or an adverse action or assessment by a regulator, an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset, and/or a current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an asset used for the purpose of producing revenue. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. Accordingly, when indicators of impairment are present, the Company would evaluate the carrying amount of these assets in relation to the operating performance of the business and estimated future undiscounted cash flows associated with the asset. If a write-down is required, the Company would prepare a discounted cash flow analysis to determine the amount of the write-down. No such impairment losses have been recognized to date.

REVENUE RECOGNITION

The Company recognizes revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements," whereby revenue is not recognized until it is realized or realizable and earned. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the buyer is fixed and determinable and collectibility is reasonably assured. Revenues from product sales are recognized upon delivery, usually upon shipment. Allowances are established for estimated uncollectible amounts, product returns and discounts. In addition, the Company defers approximately two percent of product sales as a reserve for future warranty costs and recognizes this deferred revenue over one year, which is the standard warranty period for a majority of its system components. At June 30, 2003 and 2004, the warranty reserve was approximately $633,000 and $897,000, respectively, and, historically, the warranty costs have been within management estimates.

Product sales include the sales associated with the delivery of the Company's proprietary instrument platforms for performing its diagnostic tests. In some cases, the Company has provided its instrumentation to customers without requiring them to purchase the equipment or enter into an equipment lease or rental contract. In these cases, the Company recovers the cost of providing the instrumentation in the amounts it charges for its diagnostic assays, generally under purchase and supply contracts with durations of three or more years.

Other revenue consists of research and development contracts, equipment rental and the licensing of various technologies. Research and development revenue is recorded as earned based on the performance requirements of the contract. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements. Revenue under research and development cost reimbursement contracts is recognized as the related costs are incurred.

Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

COST OF PRODUCT SALES

Cost of product sales reflects the costs applicable to products delivered for which product sales revenue is recognized in accordance with the Company's revenue recognition policy. The Company follows SFAS No. 2, "Accounting for Research and Development Costs" in classifying costs between cost of product sales and research and development costs.

SHIPPING COSTS

The Company's shipping and handling costs are included in cost of product sales for all periods presented.

RESEARCH AND DEVELOPMENT

The Company expenses its research and development costs as incurred. Research and development costs include salaries and related benefits, outside services, material and supplies and allocations of facility and support costs.

SELLING AND MARKETING

In some cases, the Company has provided its instrumentation to customers without requiring them to purchase the equipment or enter into an equipment lease or rental contract. The costs associated with the instruments are charged to selling and marketing on a straight-line basis over the estimated useful life of the instrument, which ranges from three to five years. During the years ended June 30, 2002, 2003 and 2004, these costs were $900,585, $2,268,287, and $2,615,841, respectively. The costs to maintain these systems are charged to operations as incurred.

ADVERTISING COSTS

The Company expenses advertising costs as incurred. Advertising costs amounted to approximately $963,000, $855,000 and $871,000 during the years ended June 30, 2002, 2003 and 2004 respectively.

INCOME TAXES

The Company provides for income taxes in accordance with the liability method. Under this method, deferred tax assets and liabilities are determined based on differences between 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. Substantially all of the remaining deferred tax asset valuation allowance, if released, will be reflected as a direct increase to stockholders' equity and will not impact the consolidated statement of operations.

NET INCOME (LOSS) PER SHARE

The Company follows the provisions of SFAS No. 128, "Earnings Per Share," which require the Company to present basic and diluted income (loss) per share. The Company's basic income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of Common Stock outstanding during all periods presented. The Company's diluted income (loss) per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding after giving effect to all dilutive potential common shares that were outstanding during the period. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive.

COMPREHENSIVE INCOME (LOSS)

SFAS No. 130, "Reporting Comprehensive Income," requires the presentation of comprehensive income or loss and its components as part of the consolidated financial statements. The Company's comprehensive income (loss) includes net income (loss) as well as additional other comprehensive net income (loss). For the year ended June 30, 2002, the Company's net loss approximated its comprehensive loss; accordingly, no separate disclosure of comprehensive loss is required. For the years ended June 30, 2003 and 2004, other comprehensive income (loss)

included gains and losses on long-term intercompany transactions, translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to U.S. dollars, and unrealized holding gains and losses on available-for-sale investments and are reflected net of tax.

STOCK-BASED COMPENSATION

The Company accounts for its stock-based compensation in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, compensation cost is recognized for the excess of the estimated fair value of the stock at the grant date over the exercise price, if any. The Company accounts for equity instruments issued to non-employees in accordance with EITF 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services." Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

In accordance with SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS No. 148") the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 "Accounting for Stock-Based Compensation" ("SFAS No. 123") to stock-based employee compensation is as follows:

	Year ended June 30,		
	2002	2003	2004
Net income (loss), as reported	$ (9,396,616)	$ (4,323,511)	$21,542,028
Add: Stock-based non-employee compensation included in reported net income (loss)	32,137	252,504	435,852
Deduct: Stock-based employee compensation expense if SFAS No. 123 had been applied to all grants, net of taxes	(15,086,236)	(13,310,256)	(6,897,933)
Pro forma net income (loss)	$(24,450,715)	$(17,381,263)	$15,079,947
Net income (loss) per share			
Basic—as reported	$ (0.54)	$ (0.24)	$ 1.13
Basic—pro forma	$ (1.41)	$ (0.96)	$ 0.79
Diluted—as reported	$ (0.54)	$ (0.24)	$ 1.04
Diluted—pro forma	$ (1.41)	$ (0.96)	$ 0.73

Pro forma information regarding net income and loss per share is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing fair value model. The following weighted-average assumptions were used:

	Year Ended June 30,		
	2002	2003	2004
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	79%	80%	78%
Risk-free interest rate	5.4%	2.8%	3.7%
Expected life of the option term (in years)	5.9	6.3	5.9

The effect of applying SFAS No. 123 on a pro forma net loss as stated above is not likely to be representative of the effect on reported net loss for future years due to, among other things, the vesting period of the stock options and the fair value of additional options to be granted in future years. In management's opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of the employee stock options that have vesting provisions and are not transferable. In addition, option valuation models require the input of highly subjective assumptions, and changes in such subjective assumptions can materially affect the fair value estimate of employee stock options.

RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to current year presentation.

3. Other Balance Sheet Information

INVENTORIES

Inventories consist of the following:

	June 30,	
	2003	2004
Finished goods	$ 5,132,328	$ 5,516,411
Work in process	2,897,539	3,668,683
Raw materials	1,461,347	1,207,415
	9,491,214	10,392,509
Reserve	(2,417,294)	(2,282,522)
	$ 7,073,920	$ 8,109,987

PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	June 30,	
	2003	2004
Furniture, fixtures and office equipment	$ 2,321,487	$ 3,348,037
Machinery and equipment	4,391,288	4,700,011
Customer-use assets	8,072,858	9,998,546
Leasehold improvements	201,079	2,005,455
	14,986,712	20,052,049
Accumulated depreciation and amortization	(7,471,608)	(10,490,255)
	$ 7,515,104	$ 9,561,794

Customer-use assets represent the Company's proprietary instrument platforms placed at customer sites, to which title and risk of loss is retained by the Company, for the customers' use in performing the diagnostic tests sold by the Company.

SHORT-TERM INVESTMENTS

Short-term investments at June 30, 2004 and 2003 were as follows:

	June 30, 2004			
AVAILABLE FOR SALE	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury and agencies	$ 34,162,108	$ 658	$ (86,409)	$34,076,357
Corporate debt securities	10,624,316	—	(47,074)	10,577,242
Total—Short-term investments	$44,786,424	$ 658	$(133,483)	$44,653,599

	June 30, 2004			
AVAILABLE FOR SALE	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury and agencies	$ 20,246,183	$ 9,572	$ (11,482)	$20,244,273
Corporate debt securities	6,162,811	12,828	(74)	6,175,565
Total—Short-term investments	$26,408,994	$22,400	$ (11,556)	$26,419,838

SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," requires that available-for-sale securities be recorded at market value. The Company's Short-term investments are recorded in the Consolidated Balance Sheet at fair value. As illustrated in the June 30, 2003 table above, amortized cost approximates market value. The unamortized discount was included with Short-term investments in the June 30, 2003 Consolidated Balance Sheet.

The following table summarizes the maturities of the Company's Short-term investments at June 30, 2004:

MATURITY	Amortized Cost	Fair Value
Less than one year	$32,906,562	$32,859,821
Due in one to two years	11,879,862	11,793,778
Total	$44,786,424	$44,653,599

The Company's gross proceeds from the sale of Short-term investments and the resulting realized gains and realized losses that have been included in its Consolidated Statement of Operations are as follows:

	Year Ended June 30,		
	2002	2003	2004
Gross proceeds	$4,828,083	$5,410,773	$89,827,194
Realized gains	498	640	—
Realized losses	(394)	(32)	(19)

ACCOUNTS PAYABLE

Accounts payable consist of the following:

	June 30,	
	2003	2004
Trade payables	$4,911,020	$4,261,514
Cytyc co-promotion agreement	2,298,399	—
Other	280,281	1,162,114
	$7,489,700	$5,423,628

4. Long-term Debt

In February 2000, the Company received an equipment loan facility of $1,000,000 from the State of Maryland to finance a portion of the costs of equipment installed at the Company's facility in Gaithersburg, Maryland. Approximately $503,000 of fixed asset additions, previously financed with cash, was converted to this facility during July 2000. The remaining $497,000 of the facility was drawn down in the year ended June 30, 2001 for additional capital expenditures. The repayment of this loan is secured by a lien on property and equipment purchased using the proceeds from the loan facility. The loan bears interest at 1% per annum and the Company began making quarterly principal payments in October 2002, with all unpaid principal and interest due by December 31, 2009.

In June 2002, in conjunction with the termination of Abbott Laboratories' rights with respect to the Company's HPV and chlamydia and gonorrhea products under the Abbott Agreement as discussed in Note 7, the Company repurchased equipment it sold to Abbott. In order to satisfy this obligation, the Company issued a promissory note to Abbott for $4,033,904. The note bears interest at 7% per annum and the Company is required to make quarterly installment payments of $336,159 which commenced on July 1, 2002 and will end on April 1, 2005.

In January 2003, as part of the repurchase of certain equipment from Roche Molecular Systems, Inc. under the Roche Distribution Contract as discussed in Note 7, the Company issued a promissory note to Roche with a principal amount of $1,225,663 which was paid in its entirety on January 6, 2004. There was no stated interest rate for this note and, accordingly, the Company has imputed interest at its current borrowing rate and recorded a discount on this note payable, which was amortized to interest expense over the term of the note.

At June 30, 2004, future minimum principal payments on all long-term debt obligations are as follows:

2005	$1,459,890
2006	116,429
2007	117,614
2008	118,800
2009	120,020
Thereafter	213,077
	$2,145,830

5. Income Taxes

Significant components of the provision for (benefit from) income taxes attributable to operations consist of the following:

	Year Ended June 30,		
	2002	2003	2004
Current:			
Federal	$ —	$ —	$ —
State	—	—	397,780
Foreign	210,106	223,465	175,804
Total current	210,106	223,465	573,584
Deferred:			
Federal	—	—	(12,832,429)
State	—	—	(2,066,102)
Foreign	—	—	—
Total deferred	—	—	(14,898,531)
Total provision for (benefit from) income taxes	$210,106	$223,465	$(14,324,947)

Income tax expense related to earnings of consolidated subsidiaries located outside of the United States is provided at tax rates of the respective country in which the subsidiaries are located. If the Company repatriates its investment, then additional taxes may be incurred. No provision has been reflected in the consolidated financial statements for the potential additional taxes as the Company has no specific plans for a repatriation of these investments.

The components of income (loss) from operations before income taxes are as follows:

	Year Ended June 30,		
	2002	2003	2004
United States	$(9,249,838)	$ 5,635,918	$ 21,545,679
Foreign	63,328	(9,735,964)	(14,328,598)
	$(9,186,510)	$(4,100,046)	$ 7,217,081

Items which caused recorded income taxes attributable to continuing operations to differ from taxes computed using the statutory federal income tax rate are as follows:

	Year Ended June 30,		
	2002	2003	2004
Tax (benefit) expense at statutory rates	$(3,123,000)	$(1,394,000)	$ 2,472,152
Effect of:			
State income tax, net	(335,000)	129,000	685,712
Foreign tax	210,106	223,465	175,804
Stock options	(1,604,000)	(708,000)	—
Foreign (income) loss	(22,000)	3,310,000	5,439,136
Other	1,503,000	(466,000)	571,176
Change invaluation allowance	3,581,000	(871,000)	(23,668,927)
Provision for (benefit from) income taxes	$ 210,106	$ 223,465	$(14,324,947)

For the year ended June 30, 2004, the change in the valuation allowance includes the partial reversal of the deferred tax valuation allowance of approximately $14.9 million discussed below, and the utilization of net operating loss carryforwards of approximately $8.8 million.

The Company's net deferred tax assets are as follows:

	June 30,	
	2003	2004
Net operating loss carryforwards	$ 37,013,163	$ 43,977,001
Research and development credits	2,746,073	2,808,099
Patent costs, net	220,933	183,231
Research and development deferral, net	269,304	204,437
Murex customer lists	550,486	486,352
Reserves	2,045,398	1,593,161
AMT credit	—	41,920
Other	2,472,941	2,247,810
Deferred tax assets	45,318,298	51,542,011
Valuation allowance	(45,318,298)	(36,643,480)
Net deferred tax assets	$ —	$ 14,898,531

The Company recognized an income tax benefit of $14,324,947 for the year ended June 30, 2004 and an income tax expense of $223,465 for the year ended June 30, 2003. During fiscal 2004, the Company revised its estimate of the valuation allowance previously established for the Company's deferred tax asset, resulting in an approximately $14.9 million income tax benefit. The income tax expense recorded against this benefit in fiscal 2004 related to state income taxes on the U.S. operations and income taxes on the foreign operations. The income tax expense in fiscal year 2003 primarily related to the Company's foreign operations.

At June 30, 2004, the Company had tax net operating loss carryforwards for income tax purposes of approximately $115.9 million. Approximately $90.9 million of the net operating loss carryforwards is attributable to exercised stock options, the benefit of which, if realized, will directly increase additional paid-in capital.

Substantially all of the remaining valuation allowance at June 30, 2004 related to the net operating loss attributable to exercised stock options. At June 30, 2004, the Company also had research and development credit carryforwards of approximately $2.8 million. In 1990, the Company experienced a change in ownership pursuant to Section 382 of the Internal Revenue Code, which will cause the utilization of prechange losses and credits to be limited. Subject to this limitation, the Company's net operating loss carryforwards and tax credits expire, if unused, at various dates from 2005 through 2023.

Realization of total deferred tax assets is contingent upon the generation of future taxable income. Due to the uncertainty of realization of these tax benefits, the Company did not reverse the portion of the valuation allowance for the net operating loss carryforwards and the research and development credits that are related to the exercise of stock options, and the amount of net operating loss carryforwards and research and development credits expected to expire unused.

Prior to fiscal 2004, the Company had experienced significant operating losses and operated in an industry subject to rapid technological change. Therefore, the Company believed that there was sufficient uncertainty regarding its ability to generate future taxable income and use the Company's net operating loss and tax credit carryforwards such that a full valuation allowance for deferred tax assets was required for the year ended June 30, 2003. Substantially all of the remaining deferred tax asset valuation allowance, if released, will be reflected as a direct increase to stockholders' equity and will not impact the consolidated statement of operations.

The Company reviews its deferred tax asset on a quarterly basis to determine if a valuation allowance is required, primarily based on its estimates of future taxable income. Changes in the Company's assessment of the need for a valuation allowance could give rise to adjustments to the valuation allowance and an expense in the period of change.

6. Stockholders' Equity

COMMON STOCK

On January 28, 2002, the Company issued 87,973 shares of Common Stock, valued at $2.5 million, to Abbott Laboratories in consideration for the acquisition of Abbott's exclusive marketing and distribution rights for the Company's chlamydia and gonorrhea products that were initially provided for in the Abbott Agreement. The Company accounted for the issuance of these shares as a non-cash charge to operations in its Consolidated Statement of Operations for the year ended June 30, 2002.

On January 30, 2002, the Company completed a private placement of 588,235 shares of Common Stock to certain institutional investors at $25.50 per share. The net proceeds to the Company were approximately $14.9 million. Under the Roche Distribution Contract, Roche made a non-refundable payment of $5.0 million to the Company in fiscal 2001, which was recorded as a deferred liability on the Consolidated Balance Sheet as of June 30, 2002. On July 1, 2002, consistent with the provisions of the Roche Distribution Contract, this payment was converted into 142,857 shares of Digene common stock at a conversion price of $35 per share.

The following table presents the calculation of basic and diluted net income (loss) per share:

	2002	2003	2004
Numerator:			
Net income (loss)	$(9,396,616)	$(4,323,511)	$21,542,028
Denominator:			
Weighted average shares outstanding—basic	17,360,725	18,135,689	19,144,021
Dilutive securities—stock options	—	—	1,662,057
Weighted average shares outstanding—diluted	17,360,725	18,135,689	20,806,078
Basic net income (loss) per share	$ (0.54)	$ (0.24)	$ 1.13
Diluted net income (loss) per share	$ (0.54)	$ (0.24)	$ 1.04

For the period ended June 30, 2004, outstanding stock options to purchase approximately 129,000 shares of common stock were not included in the computation of diluted net income per share because their effect would have been antidilutive since the exercise prices of such stock options were greater than the average share price of the Company's stock for the applicable period. None of the stock options outstanding for the periods ended June 30, 2002 and 2003, were included in the computation of diluted net loss per share because the effect on net loss would have been antidilutive.

COMMON STOCK OPTIONS

In March 1996, the Company adopted the Digene Corporation Omnibus Plan (the "Omnibus Plan"). Pursuant to the Omnibus Plan, officers or other employees of the Company may receive options to purchase Common Stock. The Omnibus Plan is administered by the Compensation Committee. A maximum of 2,000,000 shares have been authorized to cover grants and awards under the Omnibus Plan.

In October 1996, the Company adopted the Digene Corporation Directors' Stock Option Plan (the "Directors' Plan"). Pursuant to the Directors' Plan, directors of the Company may receive options to purchase Common Stock. Additionally, immediately following the Company's Annual Meeting of Stockholders, each non-employee director of the Company automatically is granted an option to purchase 10,000 shares of Common Stock under the Directors' Plan. The Directors' Plan is administered by the Board of Directors. A maximum of 500,000 shares have been authorized to cover grants and awards under the Directors' Plan.

In September 1997, the Company adopted the Digene Corporation 1997 Stock Option Plan (the "1997 Stock Option Plan"). Pursuant to the 1997 Stock Option Plan, consultants and other non-employees of the Company may receive options to purchase Common Stock. The 1997 Stock Option Plan is administered by the Compensation Committee. A maximum of 500,000 shares have been authorized to cover grants and awards under the 1997 Stock Option Plan.

In October 1999, the Company adopted the Digene 1999 Incentive Plan (the "1999 Plan"). Pursuant to the 1999 Plan, employees of the Company and its subsidiaries may receive options to purchase Common Stock and other Common Stock awards. The 1999 Plan is administered by the Compensation Committee. A maximum of 4,900,000 shares have been authorized to cover grants and awards under the 1999 Plan.

As of June 30, 2004, 1,935,430 shares were available for grant or award under the Omnibus Plan, the Directors' Plan, the 1997 Stock Option Plan and the 1999 Plan. Of these, 1,580,930 shares are available for grant or award to officers and employees under the Omnibus Plan and the 1999 Plan.

The terms of all stock options granted may not exceed ten years. The exercise price of options granted, as determined by the Compensation Committee, approximates fair market value of common stock at the time of the grant.

Common Stock options activity is as follows:

	Year Ended June 30,					
	2002		2003		2004	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of year	3,129,275	$16.32	3,265,862	$20.62	4,051,013	$17.95
Options granted	770,500	31.39	1,096,000	8.88	888,200	31.91
Options exercised	(541,281)	9.70	(209,623)	9.93	(1,558,710)	13.41
Options canceled or expired	(92,632)	29.03	(101,226)	22.64	(146,485)	23.12
Outstanding at end of year	3,265,862	20.62	4,051,013	17.95	3,234,018	23.74
Options exercisable at year-end	1,647,089	13.16	2,119,687	16.90	1,322,233	25.00

The following table summarizes information about fixed-price stock options outstanding at June 30, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$ 0.00–$10.00	809,898	7.4	$ 7.33	251,065	$ 8.08
$10.01–$20.00	403,232	6.8	14.54	221,042	13.32
$20.01–$30.00	606,000	8.5	27.01	59,067	27.94
$30.01–$40.00	1,362,888	8.9	33.88	785,059	33.32
$40.01–$47.63	52,000	7.6	46.98	6,000	44.25
	3,234,018			1,322,233	

The weighted-average fair values of the options granted during the years ended June 30, 2002, 2003 and 2004 were $22.36, $6.50 and $15.94 respectively.

The Company issued 25,000 stock options to a non-employee during the year ended June 30, 2003. These stock options have a vesting period of 30 months. The fair value of these stock options has been recorded as deferred compensation and is being amortized over the performance period. Under variable plan accounting, the value of the unvested stock options will be re-measured and recognized in operations at each reporting date until fully vested.

7. Commitments and Contingencies

LEASE COMMITMENTS

The Company leases a facility in Gaithersburg, Maryland, comprising a total of approximately 111,000 square feet for its corporate headquarters and manufacturing operations. The lease for the Gaithersburg facility has a ten-year term and the Company has two consecutive rights to extend the term of the lease for five years each. The Company also leases office and sales operations facilities in the United Kingdom, Germany, Switzerland, France, Brazil, Italy and Spain, which leases run in length from one year to five years. The Company also utilizes dedicated space in a third-party warehouse facility in Germany to support its European operations. Future minimum rental commitments under these and other operating lease agreements, including the agreements mentioned above, are as follows as of June 30, 2004:

2005	$ 3,407,982
2006	3,329,208
2007	3,185,531
2008	3,053,713
2009	3,078,651
Thereafter	1,761,487
	$17,816,572

Rent expense under these leases was $2,926,098, $3,174,602, and $3,448,493 for the years ended June 30, 2002, 2003 and 2004, respectively.

The Company's access to various probes, diagnostic techniques and a key product component were acquired under agreements requiring the Company to pay future royalties on future net sales on certain products. For the years ended June 30, 2002, 2003 and 2004, total royalties amounted to $2,093,434, $2,813,556, and $1,704,837, respectively.

REPURCHASE OF EQUIPMENT UNDER PRIOR MARKETING AND DISTRIBUTION AGREEMENTS

Effective May 7, 1999, the Company entered into a Marketing and Distribution Agreement ("Abbott Agreement") with Abbott Laboratories ("Abbott"). The Abbott Agreement called for Abbott to assume sales and marketing responsibility for all of the Company's Hybrid Capture products in Europe, Africa and the Middle East and for the Company's Hybrid Capture 2 chlamydia and gonorrhea tests in the United States. Abbott acted as the exclusive distributor of the Company's HPV and HBV products in Europe, Africa and the Middle East through April 30, 2001.

On April 30, 2001, the Company terminated Abbott's rights with respect to the Company's HPV products under the terms of the Abbott Agreement. This termination provided for a twelve-month non-exclusive wind-down distribution period for HPV products. In addition on April 30, 2001, the Company converted the distribution rights for the HBV products under the Abbott Agreement to non-exclusive until December 31, 2003.

On January 28, 2002, in accordance with an amendment to the Abbott Agreement, the Company terminated Abbott's exclusive rights to market, sell and distribute the Company's chlamydia and gonorrhea products worldwide, subject to a non-exclusive wind-down period for Abbott's activities with respect to such products in Europe, Africa and the Middle East that ended April 30, 2002. In connection with this amendment, the Company issued 87,873 shares of Common Stock to Abbott in a private placement transaction representing an agreed upon termination fee paid to Abbott of $2.5 million. At the expiration of the non-exclusive wind-down period the Company repurchased Digene equipment placed with customers by Abbott. Such repurchase was completed in June 2002.

On April 29, 2001, the Company entered into an agreement (the "Roche Distribution Contract") with Roche Molecular Systems, Inc. ("Roche"). Under the Roche Distribution Contract, Roche acted as a co-exclusive distributor for the Company's HPV products in Europe, Africa and the Middle East from May 1, 2001 through June 30, 2002 and the parties agreed to evaluate opportunities for a broader relationship. Roche guaranteed combined minimum purchases of equipment and HPV products over the term of the Roche Distribution Contract. The minimum purchase guarantee was funded and accounted for as follows:

	For the Year Ended June 30,	
	2001	2002
	(in thousands)	
Beginning deferred revenue	$ —	$ 7,792
Prepayments from Roche	9,728	7,272
Product sales revenue from:		
Roche	—	(5,947)
Abbott	(1,098)	(6,760)
Other revenue to Digene	(838)	(2,357)
Ending deferred revenue	$ 7,792	$ —

Under the terms of the Roche Distribution Contract, Digene was required to remit to Roche the total amount the Company received from sales made to Abbott, subject to certain limitations. Accordingly, the Consolidated Balance Sheet as of June 30, 2002 includes an amount payable to Roche of approximately $1.9 million, representing the balance of product sales revenue from Abbott which was owed to Roche.

On April 30, 2001, in accordance with the provisions of the Roche Distribution Contract, Roche made a non-refundable payment of $5.0 million to the Company, which was recorded as a deferred liability in the June 30, 2002 Consolidated Balance Sheet. The Company and Roche did not enter into the broader relationship referred to above and, therefore, in accordance with the provisions of the Roche Distribution Contract, on July 1, 2002, the $5.0 million payment was converted into 142,857 shares of Common Stock of the Company at $35 per share.

In June 2002, the Company adopted as its sole strategy for the distribution of its products in Europe, Africa and the Middle East, a combination of direct distribution through its European infrastructure and the use of local distributors and agents. On June 30, 2002, the term of the Roche Distribution Contract expired, subject to a non-exclusive wind-down period. Under the Roche Distribution Contract, the Company had the option, exercisable within 30 days after December 31, 2002, to buy back from Roche equipment purchased from the Company by Roche and in use for HPV testing in customer's laboratories on June 30, 2002. In June 2002, as part of its strategic decision, the Company decided that it would exercise the option to repurchase the equipment.

In recognition of the decision to repurchase the equipment, commencing in the fourth quarter of 2002, the Company deferred recognition of revenue from equipment sold to Roche. Equipment sold during this time period had a sales price of $2.3 million and a cost of $1.4 million, which amounts were recorded as deferred revenue and deferred costs, respectively. The deferred revenue and deferred costs were being amortized over a four-year period to other revenue (as equipment rental) and selling and marketing expenses, respectively. For the year ended June 30, 2002, the Company recorded other revenue and selling and marketing expenses of $109,000 and $67,000, respectively related to the amortization of these balances. For the year ended June 30, 2003, the Company recorded other revenue and selling and marketing expenses of $288,000 and $177,000, respectively, related to the amortization of these balances prior to the commencement of the repurchase. At December 31, 2002, when amortization ceased, the remaining deferred revenue and deferred cost balances were $1,904,000 and $1,169,000, respectively, for a remaining net credit as of December 31, 2002 of $734,000.

On December 20, 2002, Roche and Digene amended the Roche Distribution Contract to terminate the wind-down period on December 31, 2002 and to establish the procedures for Digene's repurchase from Roche of HPV-related testing equipment purchased from Digene by Roche under the Roche Distribution Contract. The repurchase price of the equipment in use for HPV testing in customers' laboratories is the equipments' December 31, 2002 depreciated value, which is the net selling price less any amounts Roche recorded as depreciation based on a straight-line basis over a four-year period. The repurchase price for the equipment in inventory is a discount from the transfer price paid by Roche under the Roche Distribution Contract.

The parties consummated the HPV equipment repurchase on January 6, 2003, subject to reconciliation. In January 2003 Digene and its affiliates paid Roche an aggregate of approximately $2.6 million for the HPV equipment in inventory and in use at customers' laboratories in Europe. A portion of the purchase price was paid by the issuance of a note payable due to Roche, which was paid in one installment in January 2004, and the remainder of the purchase price was paid in cash. A final settlement for the repurchased assets was completed with Roche in June 2003.

The total consideration paid by Digene to Roche for the fixed assets and inventory after reaching a final settlement was $2,488,000, or $1,753,000 after consideration of the remaining net credit of $734,000 mentioned above.

TENDER OFFER AND CO-PROMOTION AGREEMENT

On February 19, 2002, the Company, Cytyc Corporation ("Cytyc") and Cruiser, Inc., a wholly-owned subsidiary of Cytyc, entered into an Agreement and Plan of Merger (the "Merger Agreement"), which provided for, among other things: (i) the commencement by Cytyc of a stock and cash tender offer for all of the outstanding shares of Digene (the "Offer"); and (ii) following consummation of the Offer, the merger of Cruiser, Inc. with and into Digene. The closing of the transaction was subject to the receipt of all necessary regulatory approvals and other customary closing conditions. The transaction was reviewed by the U.S. Federal Trade Commission ("FTC") under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended.

On June 30, 2002, Digene delivered to Cytyc a formal notice of Digene's termination of the Merger Agreement following receipt of a notice from the FTC informing Digene and Cytyc that, if the parties sought to close the transactions contemplated by the Merger Agreement, the FTC would seek an injunction to block the closing. Under the terms of the Merger Agreement, each of Cytyc or Digene had the right to terminate the Merger Agreement. For the year ended June 30, 2002, the Company incurred incremental costs of approximately $3.0 million for merger related expenditures such as legal services, accounting fees and consultancy. These costs were charged to operations as incurred.

In January 2001, the Company entered into an exclusive co-promotion agreement with Cytyc for the promotion of the Company's hc_2 High-Risk HPV DNA Test for use with Cytyc's ThinPrep® Pap Test in the United States and Puerto Rico. The companies jointly promoted the benefits of testing for HPV with the Digene hc_2 High-Risk HPV DNA Test directly from Cytyc's ThinPrep Pap Test sample collection vial. Subject to FDA approval, the companies intended to co-promote the combined products as the most effective primary screening method for cervical cancer. The original term of the agreement expired June 30, 2002 and was allowed to automatically renew until June 30, 2003. This agreement was not renewed at June 30, 2003. In accordance with the co-promotion agreement, Digene paid Cytyc for its co-promotion activities based on a product sales-derived formula. For the years ended June 30, 2002 and 2003, the Company recorded expenses of approximately $1.8 million and $2.3 million, respectively, related to payments due to Cytyc for these co-promotion activities. For the year ended June 30, 2004, there were no expenses incurred.

CONTINGENCIES

The Company is involved in various claims and legal proceedings of a nature considered normal to its business including protection of its owned and licensed intellectual property. The Company records accruals for such contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available.

In March 2002, the Company filed an action for declaratory judgment against Enzo Biochem, Inc. after receiving notification that the Company had allegedly infringed one of Enzo's patents. Enzo Diagnostics, Inc. subsequently filed a complaint for patent infringement against the Company. The two cases have now been consolidated. The Court had established June 14, 2004 as a trial date in this matter. On June 10, 2004, the Court issued orders on various pretrial motions filed by the parties, including an order on a "Markman" hearing on patent claim construction for U.S. Patent No. 6,221,581. Although the Court did not adopt Digene's position on certain matters of claim construction, Digene continues to believe that it does not infringe any valid and enforceable claim of the U.S. Patent No. 6,221,581, and continues to vigorously defend against Enzo's claim of patent infringement.

On June 14, 2004, at the request of the parties, the trial was continued. An adverse outcome to such proceeding, however, could subject the Company to significant liabilities or require the Company to obtain royalty-bearing licenses, cease sales of related products or revise the applications or products which employ the technology. Digene cannot provide assurances that any such licenses would be made available to it on commercially reasonable terms, if at all, or that any such applications or products revisions could be made or be feasible.

In July 2001, Institut Pasteur notified the Company that Institut Pasteur was granted a new U.S. patent concerning the Hepatitis B virus genome and requested information from Digene regarding products that may use the technology described in such new patent. The Company and Institut Pasteur exchanged information regarding this request during the remainder of 2001 and early 2002. In July 2004, Institut Pasteur contacted the Company to renew license discussions with respect to such patent. To date, the parties have not resolved the matter. Because the Company is planning an eventual discontinuation of its Hepatitis B testing products, management currently believes the Company can resolve this matter without a material adverse effect on its results of operations or financial condition.

Through a license with Georgetown University, the Company obtained exclusive, worldwide rights to a United States patent application (subsequently issued) and corresponding foreign patents and patent applications relating to HPV type 52 and to a United States patent and corresponding foreign patents relating to the use of the L1 gene sequence to detect specific human papillomavirus types. Unless terminated earlier, the Georgetown license will terminate upon the last to expire of the licensed patent rights. The Company is obligated to make royalty payments to Georgetown University based on the percentage of net sales (as defined in the license agreement) of products incorporating the licensed technologies. The Company continues to accrue and pay its royalty obligations under this license. The Company is currently involved in negotiations with Georgetown University related to a disagreement over the calculation of such royalties. To date, such discussions have not resolved the matter. Management currently believes that the Company can resolve this matter without a material adverse effect on its results of operations or financial condition.

8. Warranties

The Company reserves 2% of product sales for future standard warranty costs. The reserve is amortized ratably over the one-year standard warranty. In fiscal 2003 the Company began to offer its customers extended warranties on its equipment. The revenue from these extended warranties is deferred and is recognized evenly over the life of the extended warranty. Changes in the Company's standard and deferred extended warranty reserves are as follows:

	For the Year Ended June 30,	
	2003	2004
Beginning deferred revenue	$ 490,432	$ 691,450
Warranties issued during the period	1,312,281	1,893,154
Changes in liability for pre-existing warranties during the period, including expirations	(1,111,263)	(1,560,539)
Ending deferred revenue	$ 691,450	$ 1,024,065

9. Sale of a Product Line

On March 24, 2000, the Company completed the sale of its Molecular Biology Reagents ("MBR") product line and related assets to KD Medical, Inc. This transaction involved the sale of the Company's MBR product line and the associated manufacturing equipment, as well as the raw material and finished goods inventory for the product line. As consideration for this sale, the Company received $200,000 in cash and a promissory note in the amount of $400,000 payable in monthly installments of $20,000 plus 8% accrued interest from July 1, 2000 through February 1, 2002. A gain of approximately $515,000 was recorded on the sale of this product line and was included in the other income (expense) line of the Consolidated Statements of Operations for the year ended June 30, 2000. In June 2002, the Company determined the balance outstanding on the promissory note was uncollectible and took a charge against operations for the unpaid principal and accrued interest of $406,500.

10. Retirement Plan

The Company sponsors a 401(k) Profit Sharing Plan (the "Plan"), which covers all employees who have completed 90 days of service. The Plan stipulates that employees may elect an amount up to 100% of their total compensation to contribute to the Plan. Employee contributions are subject to Internal Revenue Service limitations. It is recommended that elective deferral contributions not exceed between 80% and 90% of eligible pay to allow for withholding of Social Security, Federal and state taxes. This maximum deferral percentage will also allow for employer contributions, if any. All employees who have completed 1,000 hours of service during the plan year and are employed by the Company on the last day of the plan year are eligible to share in discretionary Company contributions. Employees vest in such discretionary employer contributions over five years. No contributions were made by the Company during the years ended June 30, 2002 or 2003. As of June 30, 2004, the Company recorded an accrual of approximately $50,000, for contributions to be made in the next fiscal year.

11. Significant Customers and Geographic Information

For the year ended June 30, 2002, two customers comprised 14% and 12% of total revenues, respectively. For the year ended June 30, 2003, two customers generated 18% and 10% of total revenue, respectively. For the year ended June 30, 2004, two customers generated 17% and 10% of total revenue, respectively. As of June 30, 2003 and 2004, the Company recorded receivable balances of $2,175,000 and $4,186,000, respectively, from these customers.

The Company operates one business segment that develops, manufactures and markets proprietary gene-based tests for the detection, screening and monitoring of human diseases. Worldwide operations are summarized by geographic region in the following table:

	2002		2003		2004	
	Assets	Revenues	Assets	Revenues	Assets	Revenues
North America	$61,961,002	$30,591,741	$50,845,853	$46,279,902	$ 92,526,699	$67,169,751
Europe	4,381,207	13,137,284	11,310,693	11,174,822	9,789,249	15,841,533
Latin America	899,120	2,878,867	1,170,898	2,703,297	928,048	3,292,641
Pacific Rim	—	2,239,885	47,706	2,943,875	26,252	3,856,643
	$67,241,329	$48,847,777	$63,375,150	$63,101,896	$103,270,248	$90,160,568

12. Quarterly Results of Operations (Unaudited)

The following is a summary of quarterly results of operations for the fiscal quarters (in thousands, except per share amounts):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2004				
Revenues	$19,618	$21,114	$23,565	$25,863
Net income	$ 655	$ 948	$ 2,490	$17,448
Basic net income per share	$ 0.04	$ 0.05	$ 0.13	$ 0.88
Diluted net income per share	$ 0.03	$ 0.05	$ 0.12	$ 0.83
2003				
Revenues	$12,616	$14,450	$16,982	$19,054
Net income (loss)	$(2,624)	$ (1,340)	$ (619)	$ 260
Basic net income (loss) per share	$ (0.14)	$ (0.07)	$ (0.03)	$ 0.01
Diluted net income (loss) per share	$ (0.14)	$ (0.07)	$ (0.03)	$ 0.01

The sum of basic and diluted net income (loss) per share for the four quarters in each of fiscal 2004 and 2003 may not equal basic and diluted net income (loss) per share for the year due to the changes in the number of weighted-average shares outstanding during the year.

The increase in net income from approximately $2,490,000 in the third quarter to approximately $17,488,000 in the fourth quarter in fiscal 2004 primarily relates to the partial reversal of the deferred tax valuation allowance approximating $14.9 million.

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

THE BOARD OF DIRECTORS AND STOCKHOLDERS
DIGENE CORPORATION

We have audited the accompanying consolidated balance sheets of Digene Corporation as of June 30, 2003 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2004. 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Digene Corporation at June 30, 2003 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2004, in conformity with U.S. generally accepted accounting principles.

Ernst & Young LLP

McLean, Virginia
August 5, 2004

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Form 10-K

A copy of Digene's annual report to the Securities and Exchange Commission on Form 10-K, exclusive of exhibits, is available without charge upon written request to:

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Annual Meeting

October 27, 2004

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Stock Profile and Activity

Since Digene's initial public offering of Common Stock on May 22, 1996, our Common Stock has been traded on the Nasdaq National Market under the symbol "DIGE."

The following table sets forth, for the fiscal quarters indicated, the high and low bid prices for the Common Stock, as reported by the Nasdaq National Market:

Fiscal 2005	High	Low
(through September 10, 2004)		
First quarter	$36.25	$19.88
Fiscal 2004		
Fourth quarter	$40.86	$33.02
Third quarter	48.50	29.33
Second quarter	46.24	32.59
First quarter	49.45	25.71
Fiscal 2003		
Fourth quarter	$29.05	$18.21
Third quarter	18.00	10.02
Second quarter	11.46	7.03
First quarter	11.78	6.22

On September 10, 2004, the closing sale price for the Common Stock, as reported by the Nasdaq National Market, was $24.90. As of September 10, 2004, Digene's Common Stock was held by 147 holders of record.

Digene has never paid dividends on our Common Stock and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.

Trademarks

Digene, Hybrid Capture and Rapid Capture are registered trademarks and DNAwithPap, UCM and hc_2 High-Risk HPV DNA Test are trademarks of Digene Corporation. ThinPrep and PreservCyt are registered trademarks of Cytyc Corporation. SurePath is a trademark of TriPath Imaging, Inc.

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