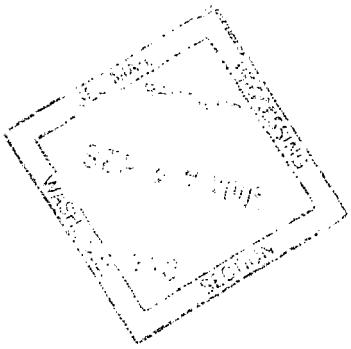
P.E. 6-30-05

MOMENTUM



ASK YOUR DOCTOR THE HPV TEST TELL YOUR FRIENDS™

2005 ANNUAL REPORT

DIGENE Corp

If there is one word that captures the spirit of what fiscal year 2005 meant for Digene, it's "momentum." A broad spectrum of partners joined us in our mission: Together, we are taking to a new level the campaign to educate both healthcare professionals and women on the emerging role of HPV testing as a standard of care in cervical cancer prevention. Signs of success are accelerating, propelling Digene into an ever-stronger position as a leader in diagnostics that promote women's health.

CORPORATE PROFILE

A leader in molecular diagnostics, Digene develops, manufactures and markets proprietary DNA and RNA tests—with a focus on women's health and infectious disease. The company's flagship product, The Digene® HPV Test (also known as DNAwithPap® Test), is the only FDA-approved test for the human papillomavirus (HPV), the primary cause of cervical cancer.

Digene's product portfolio also includes DNA tests for the detection of other sexually transmitted infections, including chlamydia and gonorrhea, as well as tests for blood viruses. Through its own staff or affiliated distributors, Digene markets its tests in more than 40 countries worldwide. Headquartered in Gaithersburg, MD, Digene is traded on NASDAQ under the symbol DIGE.

ACOG recognized HPV testing as "more sensitive than cytology"[1]

32 U.S. states passed laws or resolutions as part of the "Challenge to Eliminate Cervical Cancer," including 3 insurance mandates for HPV testing

Global HPV revenue jumped 31%

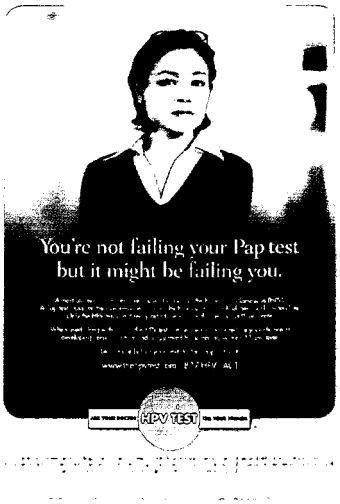
Familiarity with HPV testing increased 90% among targeted women

The Digene® HPV Test: The choice of those "in the know"

(1) American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists No. 61, April 2005.

Mobilizing Women

For the first time, there is a type of cancer that is within our ability to eliminate. We know the cause of cervical cancer, we can identify who has it, and we know who is most at risk (women age 30 and over). Polls show that once women are exposed to this information, they choose to know their HPV status. The problem: Too many women still haven't heard about HPV, much less the HPV test. In FY '05, we set out to change that.



The print ads placed in nine U.S. women's magazines beginning in the spring of FY '05 focused on two findings from consumer research: The Pap test is universally recognized by women as important to their health, but very few are aware of just what causes cervical cancer, or that the Pap alone is not enough to protect them.

The TV ad that debuted in three pilot markets—Philadelphia, Atlanta and Baltimore—re-created what naturally occurred in focus groups conducted to test Digene's creative campaign. Any time women got together to learn about HPV, the question most commonly asked was, "Why didn't I know that?" The "home movie" style of the ad reflects the spontaneous sense of empowerment generated when women talk directly to women.

We knew we had to develop a simple, straightforward message, then deliver it enough times, using vehicles women rely on and trust, to break through the clutter of health information that saturates today's environment. After the ads began appearing across the United States in national women's magazines, on TV in targeted cities and on the Internet, it soon became clear we had been successful. Research conducted in the first three TV pilots, just three months after the campaign kickoff, showed that women were responding to the call to action: "The HPV Test. Ask Your Doctor. Tell Your Friends." Sixty-five percent of the women who saw our ads said they already had received the HPV test, had called their doctors about it or planned to ask for it at their next appointment.

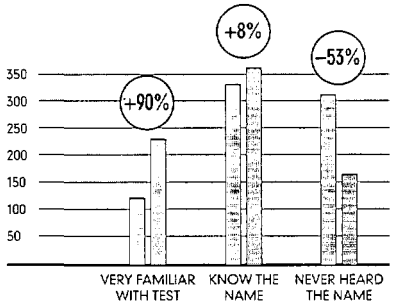
Meanwhile, our ads were reinforced by a new Web site just for women (www.TheHPVTest.com) and through increasing recognition among "earned media"—articles and broadcasts written or produced by journalists themselves. By the end of FY '05, tracking showed that 84% of all articles and broadcasts on cervical cancer highlighted the use of HPV testing for routine screening.

HPV TEST FAMILIARITY(1)

(Numbers of People)

○ BEFORE AD CAMPAIGN

○ 3 MONTHS AFTER START OF AD CAMPAIGN



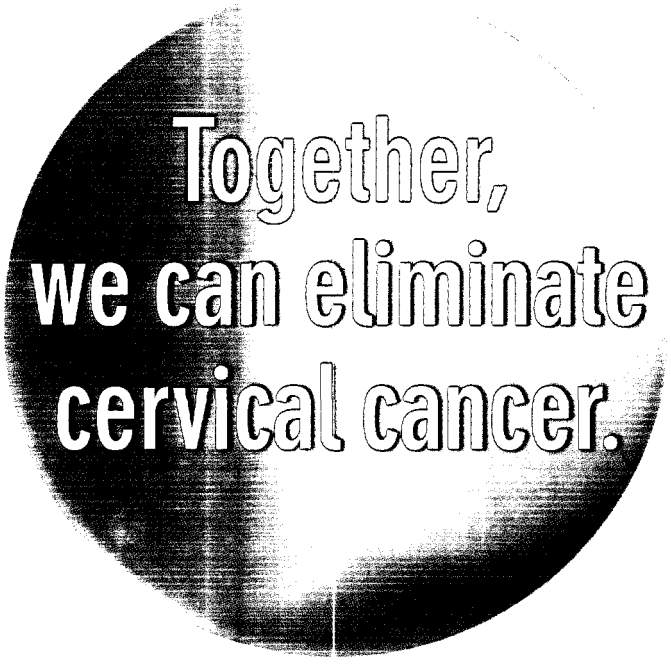
(1) Digene data.

WOMEN IN GOVERNMENT

This network of bipartisan female state legislators has adopted the elimination of cervical cancer as one of its primary goals. In January 2005, the group released "A Call to Action: The 'State' of Cervical Cancer Prevention in America." By the end of FY '05, members of Women in Government had introduced resolutions or legislation promoting cervical cancer prevention using the latest technologies in 42 states. Thirty-two passed—including three calling for mandated insurance coverage of HPV testing. Visit www.womeningovernment.org/prevention.

COALITION FOR LABOR UNION WOMEN

In an initiative called "Cervical Cancer Prevention Works," the Coalition for Labor Union Women (CLUW) is working to reduce cervical cancer rates among the more than 6 million women in union families across North America. Members are educated on HPV and cervical cancer prevention, including HPV testing, via union presentations, health fairs and conferences, as well as materials distributed through 75 chapters based in the United States and Canada. Visit www.cluw.org/cervcancer.html.



THE BALM IN GILEAD

Originally formed to help stop the spread of HIV/AIDS throughout the African diaspora by working with black churches and other faith communities, this unique organization has now expanded its work to include cervical cancer prevention. Called the ISIS Project (Intimate Sessions for Informed Sexuality), the initiative kicked off with a national advisory board on HPV and cervical cancer, a five-city "educational tour" and a training program for black women faith leaders around the country to help mobilize their congregations. Visit www.theisisproject.org.

Joining Forces

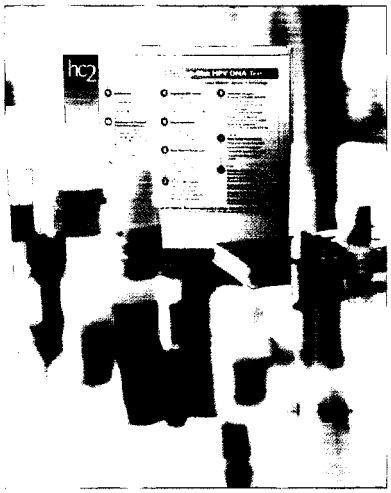
The call for HPV testing is becoming a national movement! In FY '05, several influential, independent organizations interested in women's health added their power to Digene's—reaching millions of women from different walks of life.

WOMEN'S NATIONAL BASKETBALL ASSOCIATION

The elimination of cervical cancer is a new focus of community outreach for the WNBA. A "Dream Team" of participating players—including Lisa Leslie, center for the Los Angeles Sparks and a two-time MVP—is reaching out to women through media interviews and public appearances to encourage them to talk to their doctors about cervical cancer screening and HPV testing. *Mind.Body.Spirit.* is the theme of the WNBA's community- and cause-related activities, and cervical cancer prevention is a natural fit.

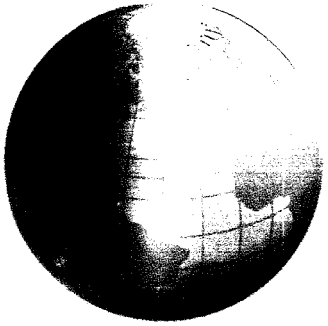
Physicians and nurses remain the key to widespread recognition and adoption of primary HPV testing as a standard of care. Incorporating routine HPV testing into their practices often requires rethinking of established procedures, and Digene facilitates that transition by positioning itself as a partner.

Motivating Healthcare Professionals



Digene's clinician sales representatives (CSRs) are chosen and trained to be more than salespersons. They are subject matter experts—equipped with the expertise and resources needed to help healthcare professionals get up to speed on the latest research and on how to apply practice guidelines, counsel their patients and strengthen the value of the annual visit. Digene's force of CSRs and managers doubled in size during FY '05, armed with new tools such as a suite of patient-education resources and a reimbursement hotline. Essential to their work are Digene's laboratory partners. They showed particular innovation this year in working with us to train their own sales forces, and in spreading the word about HPV testing to both healthcare professionals and women.

Digene's CSR force—which grew to 64 in FY '05—is key to the adoption of HPV testing by physicians and nurses. Their educational efforts are helped by the growing body of data and guidelines that support primary HPV testing—including the Practice Bulletin on HPV issued by the American College of Obstetricians and Gynecologists (ACOG) in April of 2005, which recognized primary HPV testing as more sensitive than cytology.



Going Global

Digene markets its tests in more than 40 countries worldwide. In the words of a representative of the International Agency for Research on Cancer: "...the introduction of HPV testing as the primary cervical screening test will depend on a range of local circumstances. It is likely, however, that [it] will snowball once a few populations have moved ahead and demonstrated how it can be delivered." That evidence is beginning to accumulate.

IN LATIN AMERICA, the first study of HPV testing conducted by a public health system—in this case, Brazil—was published, showing a clear advantage for The Digene® HPV Test compared to both conventional and liquid cytology.

All labeled countries are locations of Digene offices or distributors.

IN EUROPE, a study focusing on four key countries—France, the United Kingdom, Italy and the Netherlands—concluded that the addition of HPV testing, either as a follow-up to cytology or with a Pap for routine screening, can improve health at a reasonable cost. Several countries—including the United Kingdom and Italy—are going a step further and studying the use of HPV testing as a stand-alone diagnostic, with cytology as follow-up.

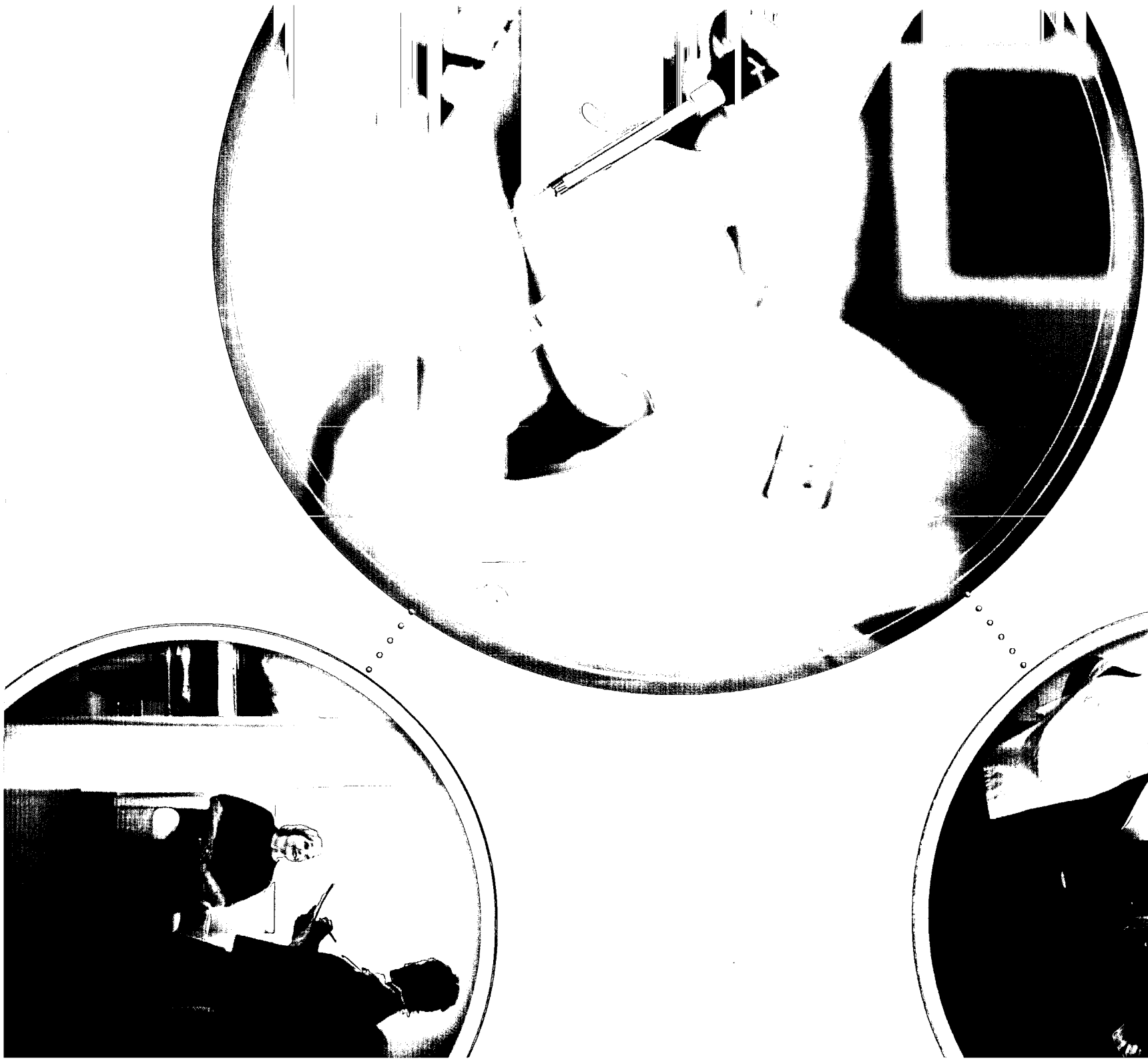
IN THE ASIA-PACIFIC region, our partner in Japan is promoting a more economic and culturally sensitive approach to screening. Only around 18% of Japanese women regularly participate in the traditional cytology-centered screening program. The new approach to HPV testing is "self-sampling," with local cancer screening centers offering follow-up and counseling. It's an innovation that is expected to have application around the world.

Photo courtesy of R. Peck, PATH

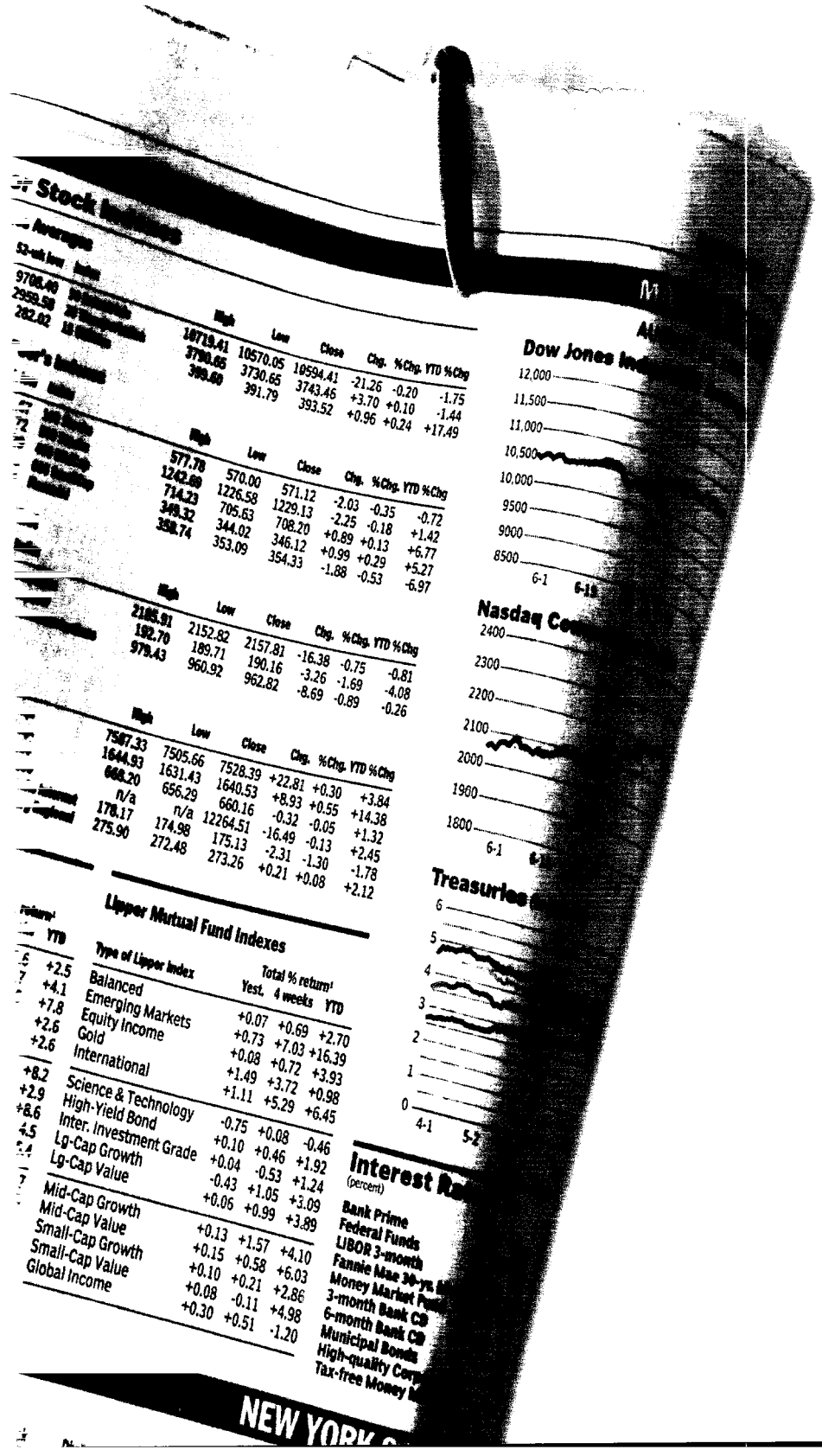
Reflecting Digene's commitment to extending the benefits of improved cervical cancer screening to women everywhere, the company is making significant progress in its partnership with PATH (Program for Appropriate Technology in Health), an international, non-profit organization whose mission is to create sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. Together, we are working to develop an HPV test customized for developing countries such as China and India. Developing countries account for 80% of all cervical cancer deaths worldwide.

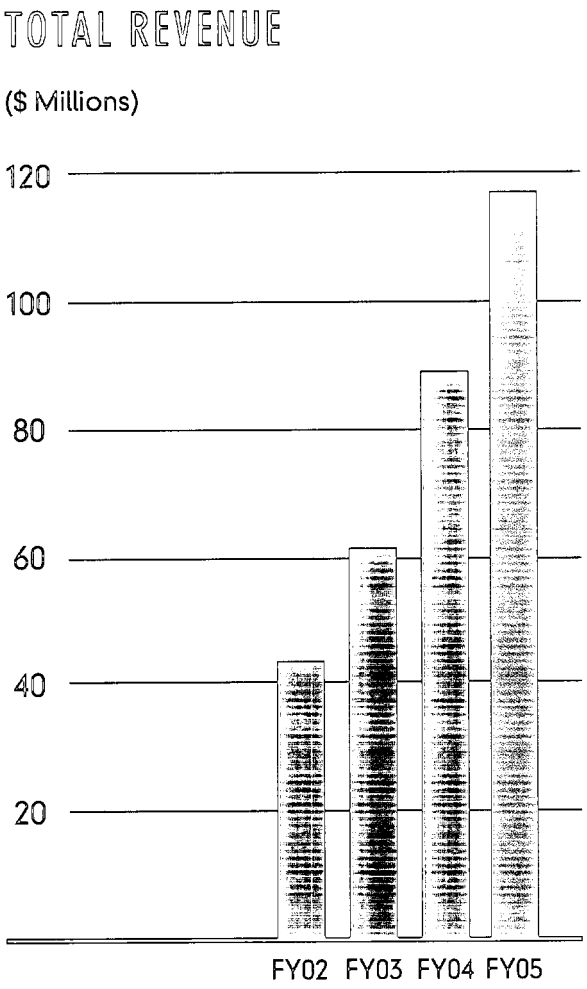
Building for the Future

The Digene vision is to significantly improve human healthcare through diagnostics, with a special focus on women's health. The company has revolutionized cervical cancer screening through gene-based HPV testing, and we plan to maintain that leadership into the future. We expect our HPV-testing technology to continue to improve, enhanced by the licensing agreement executed in FY '05 with Luminex Corporation. Luminex technology is expected to allow the Digene Hybrid Capture® platform to be used to test simultaneously for multiple diseases or health markers. Meanwhile, our genotyping reagents now under development will allow healthcare professionals to stratify which women are at highest risk, and promise to be an essential complement to future vaccines. Also on the horizon is "dcHPV"—a low-cost, easy-to-use version of Digene's HPV test for developing countries. However, Digene has aspirations beyond HPV. The company is actively looking to capitalize on its expertise in molecular diagnostics research, manufacturing and distribution by expanding into other arenas through in-licensing and acquisitions.



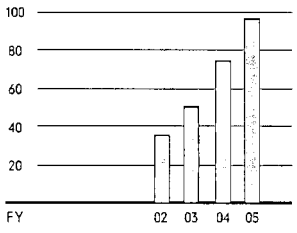
Investing in Digene



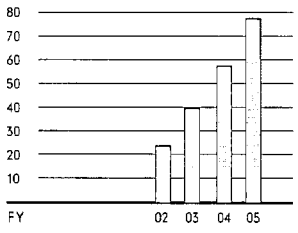


Why do we have so much confidence in Digene, and why should you? The company is a top-tier cancer-screening player with a first-mover advantage in a market estimated to represent a billion-dollar opportunity: HPV testing. We continue to offer the only FDA-approved test for high-risk HPV, the value of which has been recognized by relevant expert organizations and nearly every major insurer. We've shown our ability to capitalize on these accomplishments by building one of the fastest-growing diagnostic companies and by establishing profitable operations. Today, we have more than $46 million in cash, cash equivalents and short-term investments, and a staff that totals nearly 450 worldwide. We are continuing to fuel our growth through research and development that keeps us competitive, a commitment to quality and innovative approaches to customer education. In FY '05, our global HPV-related revenues grew 31% and the number of tests sold worldwide increased by 38%—now exceeding 5 million. This is a track record that represents momentum that can be carried over into future endeavors. Join us.

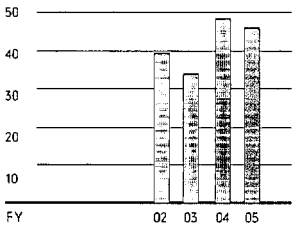
TOTAL HPV REVENUE
($ Millions)



U.S. HPV REVENUE
($ Millions)



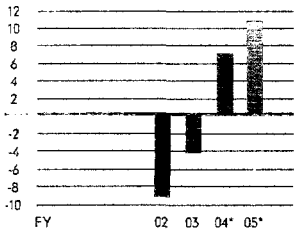
CASH, CASH EQUIVALENTS & SHORT TERM INVESTMENTS
($ Millions)



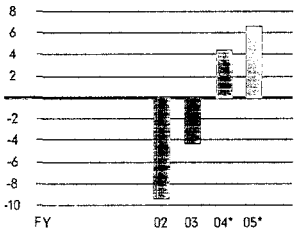
To Our Stockholders

"Momentum is building from our efforts to revolutionize cervical cancer screening with the use of our gene-based HPV tests. In the United States, we grew our HPV testing business to more than 3.5 million tests in FY '05, and we expect continued progress in 2006 and beyond."

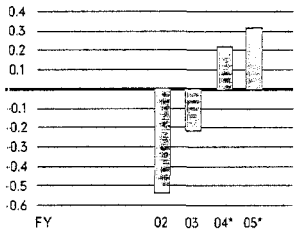
PRE-TAX OPERATING INCOME
($ Millions)



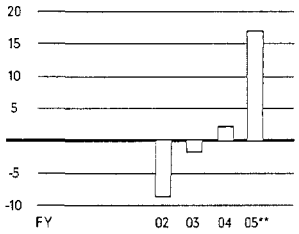
NET INCOME
($ Millions)



NET INCOME PER SHARE
($/share)



CASH FLOW FROM OPERATIONS
($ Millions)



* Excluding special items. Please see pages 51 and 52 for the reconciliation of GAAP to non-GAAP financial information.
**Excludes $14 million in patent-litigation settlement expense from the reported cash flow from operations of $2,563,403.

Fiscal 2005 was a year of great progress for Digene. We significantly grew our revenue and increased Digene's underlying profitability. This signaled a new phase in the growth of our business, as worldwide HPV test revenues increased to more than $97 million. We increased our investment in our U.S. sales and marketing infrastructure by expanding our physician detailing organization and initiating a direct-to-consumer educational campaign. The execution of these activities contributed to a 34% growth in our U.S. HPV test revenues, which exceeded $77 million, and a 28% increase in total revenue, which ended the year at more than $115 million.

During FY '05, we continued to make significant progress towards achieving our vision of improving human healthcare with our tests and building our leadership position in women's health diagnostics. Momentum is building from our efforts to revolutionize cervical cancer screening with the use of our gene-based HPV tests. In the United States, we grew our HPV testing business to more than 3.5 million tests in FY '05, and we expect continued progress in 2006 and beyond.

Our strategy and vision for the future are clear. We plan to continue our pioneering efforts to revolutionize cervical cancer screening, leverage our proven sales and marketing capabilities, and capitalize on our molecular diagnostics research, manufacturing and distribution expertise. We also are working to strengthen and expand our business

through in-licensing and acquisition activities. Digene made great progress in each of these areas during FY '05, as we describe in more detail in this letter.

Revolutionizing Cervical Cancer Screening

The benefits of HPV screening have received significant scientific and medical recognition over the past year. New clinical guidelines and studies were presented or published, including an ACOG bulletin that recognizes HPV testing as *more sensitive than cytology*, a large study from Kaiser Permanente documenting the efficacy of HPV testing for primary screening, and data from the National Cancer Institute supporting the use of HPV genotyping following a positive HPV screening test and a negative Pap.

Charles M. Fleischman, President, Chief Operating Officer, Chief Financial Officer and Director, and Evan Jones, Chief Executive Officer and Chairman of the Board of Directors

To capitalize on the medical community's growing recognition of HPV testing as an emerging standard of care, and to accelerate our commercial progress, we invested early in the fiscal year in several initiatives designed to increase HPV test sales in the United States. Our initiatives included a significant expansion of our clinician sales organization, enhanced co-marketing programs with our laboratory customers and execution of a multi-faceted marketing program. Marketing activities launched during the fiscal year included a direct-to-consumer advertising campaign, continuing medical education programs designed to help physicians get more value from patients' annual visits, and partnerships with women's advocacy organizations. These investments are paying off. For example, insurers representing more than 225 million covered lives now reimburse for primary HPV testing with a Pap. And legislation or resolutions calling for improved cervical cancer education and prevention have been passed in a number of states, including three that require insurance coverage of primary HPV testing as part of cervical cancer screening for women age 30 and older. The bottom line: Our U.S. HPV test revenue increased 19% from the first half of FY '05 to the second half, and for the full year, U.S. HPV test revenues increased 34% to more than $77 million.

The prospects for our international business also are encouraging. During FY '05, revenues for our international HPV testing business increased 21% to more than $20 million, contributing to total revenue growth of 16% to more than $26 million. We increased European HPV test revenues by 21% to more than $15 million, due to growth in countries such as Germany, Italy, Spain and France. Meanwhile, we are developing our dcHPV test in conjunction with PATH to address the growing opportunities for HPV testing in developing countries. This low-cost batch-testing system could be the key to establishing large-scale governmental HPV testing programs in low-resource settings.

Building for the Future

While we are focused on growing our existing HPV test business, we also are pursuing strategies for ensuring additional revenue streams in 2007 and beyond. For example, we are focusing our R&D investments on next-generation platforms and menu expansion. Our primary efforts include programs directed at developing improved molecular diagnostics for the detection of HPV, as well as other targets of interest in the area of women's cancers and infectious diseases.

Meanwhile, automation to aid our lab customers in processing their rapidly growing volume of HPV tests is a priority. During the year, we completed the initial development phase of a new method for processing specimens. This brings us near completion of a clinical trial to support a PMA supplement application, which we anticipate filing with the FDA in the fall of this year. Development work on instrumentation to automate this sample-preparation procedure is progressing well, and we plan to commercially launch the system in calendar 2007. We expect this system to automate the processing of 350 liquid-based Pap specimens in approximately two hours, a significant improvement over the manual method currently employed.

In May, we signed a licensing agreement with Luminex Corporation that provides Digene with access to the Luminex xMAP® bead-based multiplexing technology, allowing us to develop and commercialize next-generation products for use in women's health diagnostics. We believe this agreement marks an important milestone in the development of our next-generation Hybrid Capture® platform, known as hc4, and strategically positions the company to maintain our position as a leader in the field. We have established the technical feasibility for ultra-sensitive, multiplex detection chemistry to be used in hc4, and are transitioning to the development phase for a fully automated instrument. In addition, we are evaluating two products that can be used in the laboratory for HPV genotyping.

Strengthening Our Business

As the worldwide leader in HPV testing, Digene is uniquely positioned with strong intellectual property and market-leading tests. With the prospects for expansion of the overall field growing increasingly strong, it is critical that Digene continue to build and protect its competitive position. During the fiscal year, we announced separate settlement and licensing agreements with Enzo Biochem and Georgetown University. These agreements bring an end to the uncertainty surrounding the litigation with these parties and put Digene in a strong IP position going forward, allowing us to fully focus our efforts and resources on our HPV testing business. We believe we have taken the right path by resolving these issues. We also are actively reviewing in-licensing and acquisition opportunities that can help further strengthen our position in the field of women's health diagnostics.

Maintaining a Strong Financial Foundation

The momentum generated during FY '05 helped create record financial performance. We achieved pre-tax income, excluding the special items described below, of $10.8 million in FY '05—an increase of 49% over FY '04. Gross margin on product sales increased to 82% for FY '05, and we generated cash flow from operations of $16.6 million, excluding patent settlement costs of $14 million.

Although we reported a net loss for the year of $8.2 million, our net income for FY '05—excluding

"While we are focused on growing our existing HPV test business, we also are pursuing strategies for ensuring additional revenue streams in 2007 and beyond."

special items—was $6.7 million, or $0.32 per diluted share, compared to net income for FY '04—excluding special items—of $4.5 million, or $0.22 per diluted share. In FY '05, special items consisted of the exclusion from our GAAP results of $21.5 million in patent-litigation settlement expenses (due to separate settlement and licensing agreements with Enzo Biochem and Georgetown University) and an adjustment to reflect a 38% effective tax rate. In FY '04, special items consisted of an adjustment to reflect a 38% effective tax rate. (Please see pages 51 and 52 for the reconciliation of GAAP to non-GAAP financial information.)

We have worked hard to implement the recent advances in corporate-governance "best practices" into our operations. In June, we strengthened our Board of Directors when Frank J. Ryan became a member—bringing the number of independent directors to five. During the fiscal year, we also implemented new internal control standards mandated by the landmark Sarbanes-Oxley legislation. Beginning in FY '06, we will recognize stock option expenses in our income statement.

Making Good on the "Digene Commitment"

In fiscal 2005, we set and achieved new quality standards while shipping more than 5 million HPV tests worldwide. This accomplishment, as well as the others highlighted in this letter, represents the hard work of approximately 450 dedicated professionals employed by the company. With a worldwide network of loyal customers and collaborators, and plans to spend more than $80 million in FY '06 to develop our technology and grow our business, we are optimistic about our future.

We thank our employees, customers, collaborators and stockholders for your continuing support, and we look forward to another year of achievement.

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

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

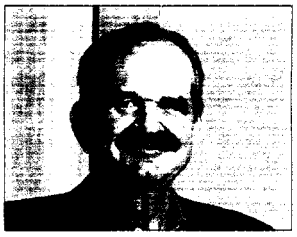
September 8, 2005

Board of Directors

Evan Jones

Charles M. Fleischman

Joseph M. Migliara



John H. Landon

John J. Whitehead

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

Cynthia L. Sullivan

Joseph M. Migliara
Private Investor

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

Kenneth R. Weisshaar

John J. Whitehead
Partner, Whitehead Partners

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

Frank J. Ryan

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

Frank J. Ryan
Former Company Group
Chairman, Johnson & Johnson

Officers

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

Vincent J. Napoleon
Senior Vice President,
General Counsel and Secretary

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 2005 Financials

Significant Product Revenues and Assets

($ in thousands)	Fiscal 2003	%	Fiscal 2004	%	Fiscal 2005	%
Product revenues from U.S. operations	$45,603	73%	$65,655	74%	$86,928	77%
Product revenues from non-U.S. operations	16,837	27%	23,160	26%	26,291	23%
Revenues from HPV test products worldwide	51,114	82%	74,581	84%	97,437	86%
Assets located in U.S.	50,843	80%	92,506	90%	92,654	87%
Assets located outside U.S.	12,532	20%	10,764	10%	14,191	13%

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, 2003, 2004 and 2005 and with respect to Digene's Consolidated Balance Sheets at June 30, 2004 and 2005 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, 2001 and 2002 and Consolidated Balance Sheet data at June 30, 2001, 2002 and 2003 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,				
	2001	2002	2003	2004	2005
	(in thousands, except per share income (loss))				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales[1]	$ 32,706	$ 45,750	$ 62,440	$ 88,815	$113,219
Distribution contract[1]	838	2,357	—	—	—
Other revenues	653	741	662	1,346	1,923
Total revenues	34,197	48,848	63,102	90,161	115,142
Costs and expenses:					
Cost of product sales[1]	12,553	12,938	13,383	16,717	20,128
Royalty and technology[1]	1,283	2,093	2,814	1,705	5,394
Research and development	8,120	9,265	10,262	10,744	12,964
Selling and marketing[1]	11,265	17,742	25,099	34,918	45,933
General and administrative	8,336	14,024	16,642	19,298	20,265
Abbott termination fee	—	2,500	—	—	—
Amortization of intangible assets	150	150	—	—	—
Patent litigation settlements	—	—	—	—	21,500
Total costs and expenses	41,707	58,712	68,200	83,382	126,184
Income (loss) from operations	(7,510)	(9,864)	(5,098)	6,779	(11,042)
Interest income	1,194	729	593	459	808
Interest expense	(11)	(32)	(273)	(184)	(37)
Other income (expense)	(37)	(20)	678	163	(116)
Income (loss) from operations before minority interest and income taxes	(6,364)	(9,187)	(4,100)	7,217	(10,387)
Minority interest	—	—	—	—	(353)
Income (loss) from operations before income taxes	(6,364)	(9,187)	(4,100)	7,217	(10,740)
Provision for (benefit from) income taxes	117	210	224	(14,325)	(2,573)
Net income (loss)	$ (6,481)	$ (9,397)	$ (4,324)	$ 21,542[3]	$ (8,167)
Basic net income (loss) per share[2]	$ (0.39)	$ (0.54)	$ (0.24)	$ 1.13	$ (0.41)
Diluted net income (loss) per share[2]	$ (0.39)	$ (0.54)	$ (0.24)	$ 1.04	$ (0.41)
Basic weighted average shares outstanding[2]	16,557	17,361	18,136	19,144	19,965
Diluted weighted average shares outstanding[2]	16,557	17,361	18,136	20,806	19,965

	2001	2002	2003	2004	2005
Consolidated Balance Sheet Data:					
Working capital	$ 26,905	$ 39,828	$ 36,119	$ 61,786	$ 52,988
Total assets	48,195	67,241	63,375	103,270	106,845
Long-term debt, less current maturities	1,000	3,690	2,154	686	572
Accumulated deficit	(61,968)	(71,365)	(75,688)	(54,146)	(62,313)
Total stockholders' equity	26,334	39,639	43,006	86,063	79,403

(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; our need to obtain third-party reimbursement approval from additional government entities, managed care organizations, and private insurance plans, particularly outside the United States; risk that other companies may develop and market human papillomavirus (HPV) tests competitive with our own; our ability to scale up our manufacturing to the extent demand for our products increases; our limited sales and marketing experience; uncertainty regarding patents and proprietary rights in connection with our products and products in development; uncertainty to the outcome of patent litigation in which we are currently engaged; 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 2006; 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. In prior years 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 HPV, which accounted for 85% of total revenues in fiscal 2005. 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 2005, our gross margin on product sales increased to 82% as compared to 81% in fiscal 2004. In fiscal 2006, we believe that we will be able to sustain a gross margin of approximately 80%. We calculate gross margin as the difference between product sales and the cost of product sales, which excludes royalty and technology expense, as a percentage of product sales for the period.

We have in-licensed patents to a number of cancer-causing human papillomavirus types, biological materials and other intellectual property on which we pay royalties, patent maintenance and other technology access costs. Our total royalty and technology expenses are expected to be approximately 5% to 6% of product sales in fiscal 2006.

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. We have also significantly expanded our sales organization in the United States and increased our investment in physician detailing and direct-to-consumer promotion activities.

During fiscal 2005 one significant area of investment was in our European infrastructure and distribution operations, in which we expect to continue to invest in fiscal 2006.

We expect to increase the size of our investment in research and development for the next several quarters and focus our research and development expenditures in the development of our next-generation Hybrid Capture platforms and other research and development programs primarily related to HPV testing.

We expect our general and administrative expenses will increase to support the overall growth of our business.

On October 13, 2004, we executed a Settlement and License Agreement to settle the then-pending patent litigation with Enzo Biochem, Inc. and its subsidiary Enzo Life Sciences, Inc. (formerly known as Enzo Diagnostics, Inc.) (collectively, Enzo). As a result, we recorded a pre-tax charge of $14 million in patent litigation settlement expense in the quarter ended September 30, 2004. Additionally, we will pay Enzo royalties on future net sales of products covered by the license grant. Please see "Liquidity and Capital Resources" below for a description of the Enzo settlement.

On July 12, 2005, we entered into a Settlement and License Agreement with Georgetown University (Georgetown) to settle the then-pending litigation. As a result, we recorded a

pre-tax charge of $7.5 million in the quarter ended June 30, 2005. We will also pay Georgetown royalties on future net sales of products covered by the license grant. Please see "Liquidity and Capital Resources" below for a description of the Georgetown settlement.

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 to generate operating profits in fiscal 2006; however, there can be no assurance that we will meet this goal.

Results of Operations

	Fiscal 2005	% change	Fiscal 2004	% change	Fiscal 2003
			(in thousands)		
Total revenue	$115,142	28%	$90,161	43%	$63,102
Product sales	113,219	28%	88,815	42%	62,440
HPV test product revenue	97,437	31%	74,581	46%	51,114
Cost of product sales	20,128	20%	16,716	25%	13,383
Gross margin[1]	82%		81%		79%
Royalty and technology expense	$ 5,393	216%	$ 1,705	(39)%	$ 2,814

(1) We calculate gross margin as the difference between product sales and the cost of product sales, which exclude royalty and technology expense, as a percentage of product sales for the period.

COMPARISON OF FISCAL YEAR ENDED JUNE 30, 2005 TO FISCAL YEAR ENDED JUNE 30, 2004

Product sales in fiscal 2005 increased 28% as compared to fiscal 2004. The increase was due primarily to a 31% growth in sales of our HPV test products to approximately $97,437,000. An increase of 21% in equipment sales, to approximately $6,565,000, also contributed to the increase in product sales. The majority of the growth in our HPV test product revenue was in the United States, which increased 34% to approximately $77,301,000, and in Europe, which increased 21%, to approximately $15,613,000. In the United States, most of the growth in our HPV test product sales was from increased acceptance of our Digene HPV Test (also marketed as the DNAwithPap™ Test in the United States) 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. We believe the continued growth was also due in part to our direct-to-consumer marketing campaign which began in fiscal 2005. 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. The net impact of foreign exchange rate fluctuations on product sales was immaterial for the fiscal years ended June 30, 2005 and 2004, respectively.

Other revenues primarily include research and development contract revenues, equipment rental revenues and licensing revenues. Other revenues increased 43% in fiscal 2005 to approximately $1,923,000 from approximately $1,345,000 in fiscal 2004. The increase in other revenues in fiscal 2005 is largely due to a 29% increase in research and development contract revenues to approximately $731,000, and a 149% increase in miscellaneous revenue to $313,000, which consists primarily of extended warranty revenue.

Cost of product sales in fiscal 2005 increased 20% as compared to fiscal 2004 primarily due to increased product sales volume. Gross margins on product sales increased to 82% in fiscal 2005 from 81% in fiscal 2004. The increase in gross margin percentage in fiscal 2005 was the result of a shift in product mix from lower margin products to higher margin HPV test products. This increase in gross margin percentage due to product mix changes was partially offset by increased manufacturing overhead costs.

Royalty and technology expense increased 216% to approximately $5,393,000 in fiscal 2005 from approximately $1,705,000 in fiscal 2004. The increase in fiscal 2005 was primarily due to increased royalty expenses, effective October 1, 2004, on net sales of our products based on a Settlement and License Agreement with Enzo, under which we pay Enzo royalties on net sales of products covered by the license grant. The increase is also due to a charge of $750,000 accrued during the quarter ended September 30, 2004 relating to a non-exclusive license to Institut Pasteur's intellectual property concerning the Hepatitis B virus genome and the reversal of approximately $535,000 of accrual during the prior fiscal year based on the expectation that a specific royalty accrual would not materialize. Please see "Liquidity and Capital Resources" below for a description of the Enzo settlement.

Research and development expenses increased 21% in fiscal 2005 to approximately $12,964,000 from approximately $10,744,000 in fiscal 2004. The increase in expenditures was due primarily to a 17% increase in personnel costs to approximately $5,919,000, an increase in professional services of 36% to approximately $2,608,000, and an increase in license fees to $402,000. The increase in professional services was due largely to costs paid to a vendor for development of a sample preparation workstation, clinical evaluations for processing liquid-based cytology, and costs incurred for the preparation of compliance with the European Union In Vitro Diagnostic

Directive regulations for our Rapid Capture® System and related accessories, for which compliance was obtained in the last quarter of fiscal 2005. The majority of the license fees relate to a supply and license agreement we entered into in fiscal 2005 to develop certain next-generation products.

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 2005 our research and development activities focused on our platform technology, including adaptations of such technology, and improvements to our diagnostic test and equipment products. We focused our research and development activities in four areas: (1) core research efforts for next-generation technologies; (2) new product development activities; (3) support and improvement of existing product lines and equipment offerings; and (4) support of regulatory submissions to seek approvals to market our existing products for additional uses and indications in the U.S. and abroad.

Our core research efforts for next-generation technologies include research programs for improved molecular diagnostic assay systems for 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. We completed initial technical feasibility of our proprietary next generation DNA test platform for ultra-sensitive detection of DNA targets in a multiplexed format and we are conducting further evaluations to confirm the applicability of the new method and are entering the product development stage. We are working on products that will enable HPV genotyping, and have two products in the development pipeline. We continue our collaborative product development and commercialization agreement with PATH (Program for Appropriate Technology in Health) to develop a rapid, batch HPV test for resource constrained countries and have entered the second year of that program. Digene and PATH jointly fund the efforts subject to certain maximum funding obligations and Digene performs the product development and commercialization activities.

Product development activities are currently focused on improving and simplifying cervical specimen processing procedures and increasing Hybrid Capture 2 assay throughput, including a new batch preparation method for processing liquid-based cytology specimens for Hybrid Capture testing. In support of this new method, we are conducting a multicenter clinical evaluation specifically for the processing of cervical specimens collected in ThinPrep® PreservCyt® Solution (Cytyc Corporation). The results of this study will support a pre-market approval supplement (PMA supplement) for the Hybrid Capture 2 testing of PreservCyt Solution specimens processed in this manner and is expected to lead to a FDA submission in fiscal 2006. This processing method is expected to become part of a more comprehensive clinical sample preparation workstation also in development, which is being designed to automate the front-end processing of all clinical specimen types for HPV, chlamydia (CT), and gonorrhea (GC) testing, including specimens collected in our Specimen Transport Media (STM). This sample preparation workstation is intended to provide a streamlined means to prepare samples for transfer to the Rapid Capture System. We have also begun validation of the next version of Digene Microplate Luminometer software, which is expected to provide new features and improvements in the data acquisition and result reporting capabilities from our luminometer.

We are continuing efforts to expand HPV testing capabilities for additional liquid-based cytology media, including the SurePath™ collection and preservative medium (TriPath Imaging). The regulatory work required to obtain FDA approval for use of SurePath for HPV testing following TriPath Imaging's voluntary withdrawal of their PMA supplement in February 2005 is ongoing as part of the continued collaboration between Digene and TriPath Imaging.

Regulatory work was also completed in late fiscal 2005 that enabled the Rapid Capture System and associated products to be sold in the European Union.

Selling and marketing expenses increased 32% in fiscal 2005 to approximately $45,933,000 from approximately $34,918,000 in fiscal 2004. The increase in fiscal 2005 was due primarily to personnel costs, which increased 45% to approximately $14,775,000; marketing program expenses, which increased 63% to approximately $11,531,000; and facility and overhead costs, including travel, which increased 29% to approximately $9,875,000. The increase in personnel costs is due largely to increasing the size of our physician detailing sales force for which we began hiring extensively in the middle of fiscal 2005. The increase in marketing program expenses is the result of a direct-to-consumer awareness campaign implemented during the quarter ended March 31, 2005. These increases were partially offset by a 12% decrease in agency fees to approximately $4,800,000, for our physician detailing arrangement with PDI, Inc. PDI recruits and administers a Digene-specific physician education sales organization dedicated to educating physicians about the benefits of The Digene HPV Test in the United States.

Geographically, the majority of the increase in our selling and marketing expenses for fiscal 2005 was incurred in the United States, which increased 40% to approximately $30,859,000 as compared to approximately $22,051,000 in fiscal 2004, as we expanded our direct sales and marketing activities, including our direct-to-consumer awareness campaign, in the United States to increase sales of our HPV test products.

General and administrative expenses increased 5% in fiscal 2005 to approximately $20,265,000 from approximately $19,298,000 in fiscal 2004. The increase was due primarily to personnel costs, which increased 20% to approximately $8,795,000 and an 18% increase in facility and overhead costs to approximately $3,198,000. These increases were partially offset by a 13% decrease in professional services, to approximately $6,632,000. The decrease in professional services is due largely to a decrease in legal fees, which decreased 28% to approximately $4,380,000, partially offset by an increase in accounting fees, which increased 56% to approximately $1,399,000.

Geographically, the majority of the increase in general and administrative expenses for fiscal 2005 was incurred in the United States, which increased 6%, to approximately $13,109,000, over the corresponding period in fiscal 2004.

Patent litigation settlements relate to the October 2004 settlement with Enzo, for which $14,000,000 was recorded in the first quarter of fiscal 2005, as well as a charge of $7,500,000 recorded in the last quarter of fiscal 2005 based on a Settlement and License Agreement entered into with Georgetown on July 12, 2005. Please see "Liquidity and Capital Resources" below for descriptions of the Enzo and Georgetown settlements.

Interest income increased 76% to approximately $808,000 in fiscal 2005 from approximately $459,000 in fiscal 2004. The increase was due to higher interest rates in fiscal 2005 compared to the corresponding period in fiscal 2004, as well as higher average short-term investment balances in fiscal 2005 compared to fiscal 2004.

Interest expense decreased to approximately $37,000 in fiscal 2005 compared to approximately $184,000 in fiscal 2004 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. The promissory note was paid in full in September 2004.

Other expense was approximately $116,000 in fiscal 2005 and other income was approximately $162,000 in fiscal 2004. The balances in both periods are primarily based on foreign exchange rate fluctuations causing transaction gains and losses.

Minority interest was approximately $353,000 in fiscal 2005. Minority interest represents the Digene do Brasil LTDA minority partner's share of the equity and earnings of the subsidiary.

The net income tax benefit of approximately $14,325,000 in fiscal 2004 was 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 which was the estimated amount to be utilized in the foreseeable future. Based upon projected future operating performances, we believed, and despite fiscal 2005 operating losses still believe, that we will be able to utilize a portion of the value of our net operating loss (NOL) carryforward against future taxable income. Accordingly, we recognized an income tax benefit of approximately $2,574,000 in fiscal 2005. However, we recognized approximately $4,283,000 of foreign operating losses before income tax from European operations during fiscal 2005 that did not generate an income tax benefit due to a full valuation allowance reported against foreign deferred tax assets, including additional deferred tax assets created by current year foreign tax losses. As of June 30, 2005 and June 30, 2004, we had total U.S. NOL carryforwards of approximately $113,394,000 and $115,851,000, respectively. We also had foreign NOL carryforwards of approximately $22,181,000 and $18,543,000 as of June 30, 2005 and June 30, 2004, respectively. For fiscal 2005 and 2004, we have not reversed 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 and the amounts are expected to expire unused. Should realization of these benefits become more likely than not, the benefit will be reflected as a reclassification to stockholders' equity. Further, we have not reversed any portion of the valuation allowance related to foreign NOLs; should realization of these benefits become more likely than not, the benefit will be reflected as an increase to consolidated statement of operations.

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

Product sales in fiscal 2004 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 Digene HPV Test for adjunctive cervical cancer screening with a Pap test for women age 30 and older, an indication approved by the 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 included 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 included 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.

During fiscal 2004, our new product development activities focused 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 included 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 also worked 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 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 PMA 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 and gonorrhea 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 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 related to our increased hiring activities. The increase in agency fees related to costs under our physician detailing agreement with PDI, Inc. PDI recruited and administered a Digene-specific physician detailing sales organization dedicated to educating physicians about the benefits of The Digene HPV Test in the United States. The professional services increase was 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.

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 was 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. In fiscal 2003, the entire deferred tax asset was fully reserved with a valuation allowance; the $223,000 tax provision related exclusively to foreign tax from our Brazilian operations. Based upon projected future operating performances, we believed that we would be able to utilize a portion of the value of our NOL carryforwards 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 U.S. NOL carryforwards of approximately $115,851,000; 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 was not likely at the time and the amounts are expected to expire unused. Should realization of these benefits become more likely than not, the benefit will be reflected as a reclassification to stockholders' equity.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of approximately $62,313,000 at June 30, 2005. 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, 2005, we had cash, cash equivalents and short-term investments aggregating approximately $46,082,000. We had positive cash flows from operations of approximately $2,563,000 for the year ended June 30, 2005 compared to positive cash flows from operations of approximately $2,064,000 for the year ended June 30, 2004.

Net cash provided by investing activities for fiscal 2005 of approximately $9,190,000 included $14,000,000 of net sales and maturities of short-term investments to pay patent

litigation settlement expenses, as more fully described below, partially offset by approximately $5,218,000 of capital expenditures. In fiscal 2006, we expect to spend a significant amount of working capital as we further expand our warehouse capacity at our Gaithersburg facility, for which we may obtain alternative financing.

On October 13, 2004 we entered into a Settlement and License Agreement to settle our patent litigation with Enzo. Under the Agreement with Enzo, we received an irrevocable, non-exclusive, royalty-bearing worldwide license under identified Enzo patents. We made an initial payment to Enzo of $16,000,000, of which $2,000,000 can be used to offset future royalty payments under the terms of the Agreement, resulting in a one-time pre-tax charge of $14,000,000 in patent settlement expense. We will also pay Enzo royalties on future net sales of products covered by the license grant, which royalties will be at least $2,500,000 for the first annual period (October 1, 2004 to September 30, 2005) and at least $3,500,000 for each of the next four annual periods. We are obligated to make such guaranteed minimum payments in such first five annual periods under the Enzo Agreement. Our obligation to make royalty payments will end on April 24, 2018, unless earlier terminated in accordance with the terms of the Enzo Agreement.

On July 12, 2005 we entered into a Settlement and License Agreement with Georgetown. Under the Agreement with Georgetown, we were granted irrevocable, world-wide, exclusive, royalty-bearing licenses with the right to grant sublicenses under two Georgetown patents, as well as corresponding foreign patents and patent applications. Under the Georgetown Agreement, we made an initial payment of $3.75 million in July 2005, and we will make a second payment to Georgetown no later than October 15, 2005. We recorded a pre-tax charge of $7.5 million in settlement expense in our fiscal 2005 fourth quarter results. Digene will also pay Georgetown royalties on future net sales of products covered by the license grants. Our obligation to make royalty payments on one of the patents will end on October 15, 2008 and for the other patent on July 1, 2014, unless earlier terminated in accordance with the terms of the Georgetown Agreement.

In August 2004, we established a leasing facility with ePlus Group, Inc. with a total commitment of $1,000,000. We intend to use such facility to fund the lease of computer hardware and associated software. As of June 30, 2005, we have used approximately $561,000 of such commitment.

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 co-exclusive distributor of our 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 non-exclusive 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 are currently in negotiations with our landlord to expand the manufacturing and research and development space at our Gaithersburg facility. It is likely that we will execute an amendment to our existing lease which will extend the term of the lease beyond our existing commitment and require us to contribute financing to the expansion. Our Gaithersburg facility is currently accounted for as an operating lease, and it is anticipated that under the terms of the proposed lease amendment, we will be required to prospectively account for the lease as a capital lease. If our lease does convert to a capital lease, we will record the fair value of the building on our balance sheet and also record the related lease obligation as a liability. The financial statement impact of this transaction has not yet been determined but is expected to be material.

We anticipate that working capital requirements will increase moderately for the foreseeable future due to the investment necessary to expand our Gaithersburg facility, as well as increasing accounts receivable as a result of expected revenue growth. 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 2006. 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; the effectiveness of our sales and marketing activities; 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 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, which could include public offerings of our securities using our effective shelf registration statement, strategic alliances with corporate partners and others, or through other sources. Other than our equipment leasing facility with ePlus Group, Inc., 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 would be materially adversely affected.

We have summarized below our material contractual obligations as of June 30, 2005:

Contractual Obligations	Total	Less than One Year (Fiscal 2006)	One to Three Years (Fiscal 2007–2009)	Four to Five Years (Fiscal 2010–2011)	After Five Years (After Fiscal 2012)
Long-term debt	$ 687,660	$ 116,036	$ 356,827	$ 214,797	$ —
Physician detailing agreement	342,246	342,246	—	—	—
Operating leases	15,205,226	3,566,728	9,850,185	1,748,749	39,564
Minimum royalty payments[1]	15,454,377	1,454,377	10,500,000	3,500,000	—
Total contractual cash obligations	$31,689,509	$5,479,387	$20,707,012	$5,463,546	$39,564

(1) On October 14, 2004, we paid Enzo $16 million under the terms of the Agreement with Enzo. Of the $16 million payment, $2 million is being used to offset future minimum royalty payments.

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.* 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.
- *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 $17,381,000 and $27,519,000 during our fiscal years ended June 30, 2003 and 2005, 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 loss which approximated $4,324,000 and $8,167,000 during our fiscal years ended June 30, 2003 and 2005, 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 $14,325,000 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 and 2005 we have provided a valuation allowance against the U.S. net operating loss carryforwards and research tax credits related to the exercise of stock options as well as other U.S. net operating loss carryforwards and tax credits expected to expire unused. We have also provided a valuation allowance against foreign net operating loss carryforwards 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 recent historical financial trends and 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. A significant portion 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 remaining valuation allowance, if released, will be reflected as an increase to book income and will 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, 2003, 2004 and 2005. Interest rate exposure is primarily limited to the $46.1 million of cash, cash equivalents and short- and long-term investments owned by us as of June 30, 2005. 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, 2004	June 30, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,079,519	$ 15,789,473
Short-term investments	44,653,599	30,292,421
Accounts receivable, less allowance of approximately $600,000 and $288,000 at June 30, 2004 and 2005, respectively	17,545,133	20,296,303
Inventories, net	8,109,987	7,197,388
Prepaid expenses and other current assets	2,392,048	3,129,382
Deferred tax asset, current	1,047,766	2,037,718
Total current assets	77,828,052	78,742,685
Property and equipment, net	9,561,794	10,104,045
Deposits and other assets	2,150,486	2,237,462
Deferred tax asset, net	13,729,916	15,761,238
Total assets	$103,270,248	$106,845,430
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,423,628	$ 7,807,316
Accrued expenses	3,771,141	11,996,460
Accrued payroll	5,387,129	5,835,295
Current portion of long-term debt	1,459,890	116,036
Total current liabilities	16,041,788	25,755,107
Deferred rent	479,078	763,112
Long-term debt, less current portion	685,940	571,624
Minority interest	—	353,033
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, 19,883,918 and 20,037,253 shares issued and outstanding at June 30, 2004 and 2005, respectively	198,839	200,373
Additional paid-in capital	139,637,245	140,914,008
Deferred stock compensation	(164,031)	—
Accumulated other comprehensive income	537,688	601,342
Accumulated deficit	(54,146,299)	(62,313,169)
Total stockholders' equity	86,063,442	79,402,554
Total liabilities and stockholders' equity	$103,270,248	$106,845,430

See accompanying notes.

Consolidated Statements of Operations

	Year Ended June 30,		
	2003	2004	2005
Revenues:			
Product sales	$62,440,415	$ 88,815,293	$113,218,813
Other	661,481	1,345,275	1,922,790
Total revenues	63,101,896	90,160,568	115,141,603
Costs and expenses:			
Cost of product sales	13,383,086	16,716,387	20,127,590
Royalty and technology	2,813,556	1,704,837	5,393,343
Research and development	10,262,138	10,743,763	12,963,915
Selling and marketing	25,099,168	34,918,406	45,932,993
General and administrative	16,642,100	19,297,782	20,265,277
Patent litigation settlements	—	—	21,500,000
Total costs and expenses	68,200,048	83,381,175	126,183,118
Income (loss) from operations	(5,098,152)	6,779,393	(11,041,515)
Other income (expense):			
Interest income	593,331	459,170	807,576
Interest expense	(272,810)	(183,945)	(37,105)
Other income (expense)	677,585	162,463	(116,468)
Total other income (expense)	998,106	437,688	654,003
Income (loss) from operations before minority interest and income taxes	(4,100,046)	7,217,081	(10,387,512)
Minority Interest	—	—	(353,033)
Income (loss) from operations before income taxes	(4,100,046)	7,217,081	(10,740,545)
Provision for (benefit from) income taxes	223,465	(14,324,947)	(2,573,675)
Net income (loss)	$ (4,323,511)	$ 21,542,028	$ (8,166,870)
Basic net income (loss) per share	$ (0.24)	$ 1.13	$ (0.41)
Diluted net income (loss) per share	$ (0.24)	$ 1.04	$ (0.41)
Weighted average shares outstanding			
Basic	18,135,689	19,144,021	19,964,800
Diluted	18,135,689	20,806,078	19,964,800

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, 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
Comprehensive loss:							
Foreign currency translation	—	—	—	—	36,291	—	36,291
Unrealized gain on available for-sale securities, net of income tax benefit of $33,402	—	—	—	—	27,363	—	27,363
Net loss	—	—	—	—	—	(8,166,870)	(8,166,870)
Comprehensive loss							(8,103,216)
Exercise of Common Stock options	153,335	1,534	1,530,013	—	—	—	1,531,547
Compensatory stock options earned by non-employees	—	—	(253,250)	164,031	—	—	(89,219)
Balance at June 30, 2005	20,037,253	$200,373	$140,914,008	$ —	$601,342	$(62,313,169)	$79,402,554

See accompanying notes.

Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2003	2004	2005
OPERATING ACTIVITIES			
Net income (loss)	$ (4,323,511)	$ 21,542,028	$ (8,166,870)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization of property and equipment	3,293,454	3,914,062	4,490,281
Amortization of discount on note payable	—	35,603	—
Loss on disposal of fixed assets	22,925	178,036	259,454
Compensation expense related to stock options	252,504	435,852	(89,219)
Deferred tax benefit	—	(14,898,531)	(2,867,024)
Minority interest	—	—	353,033
Changes in operating assets and liabilities:			
Accounts receivable	(1,343,013)	(7,200,536)	(2,681,183)
Inventories	259,177	(1,036,067)	1,009,253
Prepaid expenses and other current assets	6,039	(202,823)	(781,609)
Deposits and other assets	(233,725)	(190,305)	(88,730)
Accounts payable	993,294	(2,066,072)	2,173,658
Accrued expenses	(2,161,077)	303,512	8,203,996
Accrued payroll	1,317,891	1,204,802	464,329
Deferred rent	81,832	44,170	284,034
Net cash provided by (used in) operating activities	(1,834,210)	2,063,731	2,563,403
INVESTING ACTIVITIES			
Purchases of short-term investments	(29,940,689)	(52,712,116)	(23,899,798)
Sales and maturities of short-term investments	33,671,809	34,334,686	38,308,066
Capital expenditures	(3,763,786)	(6,138,788)	(5,218,110)
Net cash used in investing activities	(32,666)	(24,516,218)	9,190,158
FINANCING ACTIVITIES			
Exercise of Common Stock options	2,081,787	20,898,310	1,531,547
Principal payments of long-term debt	(1,428,492)	(2,684,380)	(1,458,172)
Net cash provided by financing activities	653,295	18,213,930	73,375
Effect of currency translations	(356,415)	434,947	(116,982)
Net increase (decrease) in cash and cash equivalents	(1,569,996)	(3,803,610)	11,709,954
Cash and cash equivalents at beginning of year	9,453,125	7,883,129	4,079,519
Cash and cash equivalents at end of year	$ 7,883,129	$ 4,079,519	$ 15,789,473
SUPPLEMENTAL CASH FLOW INFORMATION			
Interest paid	$ 374,000	$ 163,000	$ 46,000
Income taxes paid	$ 149,000	$ 345,000	$ 202,000

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.

On April 26, 2002, the Company established a wholly-owned subsidiary, Digene UK (Holdings) Limited, as a holding company for most of 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 accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements. These estimates include assessing the collectibility of accounts receivable and valuation of inventories and long-lived assets and the provision for warranty obligations. 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 (loss). Certain transaction gains and losses on intercompany activity for which settlement is not planned in the foreseeable future are included as a separate component of stockholders' equity in accumulated other comprehensive income in the accompanying balance sheets.

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 highly rated financial 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, 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 results of 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 as interest income 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 management's expectations of losses. Losses have historically been minimal and within management's expectations. As of June 30, 2004 and 2005, the Company had an allowance for doubtful accounts of approximately $600,000 and $288,000, respectively.

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 10.

CONCENTRATION OF CREDIT RISK AND FINANCIAL INSTRUMENTS

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company limits its exposure to credit loss by placing its cash and cash equivalents with high credit quality 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.

FAIR VALUE OF FINANCIAL INSTRUMENTS

The fair value of the Company's accounts receivable, accounts payable and accrued expenses 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, 2004 and 2005 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 a limited number of suppliers. This applies in particular to three components: chemiluminescent substrates (used to create a chemical reaction that generates 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 using actual 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 straight-line method over the estimated useful lives of three to ten years. Leasehold improvements are amortized over the lesser of the related lease term, including any lease term extensions that the Company has the right and intention to execute, or the useful life. Construction in-process relates to the assets acquired to facilitate expansion of the Company's Gaithersburg, Maryland facility. Repairs and maintenance expenditures are charged to operations as incurred.

INTANGIBLE ASSETS

Intangible assets, which are included in deposits and other assets in the Consolidated Balance Sheets, 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 amortized on a straight-line basis over ten years until June 2002. Goodwill and intangible assets deemed to have an indefinite useful life are reviewed for impairment in the fourth quarter of each fiscal year. The Company reviewed the value of the intangible assets in the fourth quarter of fiscal year 2004 and 2005 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 and 2005.

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.

MINORITY INTEREST

Minority interest represents the Digene do Brasil LTDA minority partner's share of the equity and earnings of the subsidiary.

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, 2004 and 2005, this warranty reserve was approximately $897,000 and $1,137,000, 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 Statement of Financial Accounting Standards ("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, net of amounts billed to customers, are included in cost of product sales and totaled $1,227,998, $1,574,450, and $1,832,325 for the years ended June 30, 2003, 2004, and 2005, respectively.

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. The Company does not track separately the costs applicable to collaborative research revenue as there is not the distinction between the Company's internal development activities and the development efforts made pursuant to agreements with third parties.

SELLING AND MARKETING

In some cases, the Company has provided its instrumentation, to which the Company retains title, to customers without requiring them to purchase the equipment or enter into an equipment lease or rental contract. The costs associated with these instruments are capitalized and 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, 2003, 2004 and 2005, these costs were $2,268,287, $2,615,841 and $2,828,998, 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 $855,000, $871,000 and $4,434,000 during the years ended June 30, 2003, 2004 and 2005, 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. A significant portion of the remaining deferred tax asset valuation allowance, if released, will be reflected as an increase to stockholders' equity and will not impact the Consolidated Statement of Operations.

NET INCOME (LOSS) PER SHARE

The Company computes net income (loss) per share in accordance with SFAS No. 128, "Earnings Per Share," and SEC Staff Accounting Bulletin No. 98 ("SAB No.98"). SFAS No. 128 requires 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 Stockholders 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.

Under the provisions of SAB No. 98, common shares issued for nominal consideration, if any, would be included in the per share calculations as if they were outstanding for all periods presented. The Company considers common equivalent shares from the exercise of stock options in the instance where the shares are dilutive to net income of the Company by application of the treasury stock method.

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 years ended June 30, 2003, 2004 and 2005 other comprehensive income (loss) included gains and losses on intercompany transactions with foreign subsidiaries considered long-term investments, translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar, and unrealized holding gains and losses on available-for-sale investments. The unrealized holding gains and losses on available-for-sale investments 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 ("APB 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. Because the Company establishes the exercise price of stock options based on the fair market value of the Company's Common Stock on the date of the grant, the stock options have no intrinsic value and therefore no expense is recorded.

The Company accounts for equity instruments issued to non-employees in accordance with Emerging Issues Task Force 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" the effect on net income (loss) and net income (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 "Accounting for Stock-Based Compensation" to stock-based employee compensation is as follows:

	Year Ended June 30,		
	2003	2004	2005
Net income (loss), as reported	$ (4,323,511)	$21,542,028	$ (8,166,870)
Add: Stock-based non-employee compensation expense included in reported net income (loss), net of taxes	252,504	435,852	(54,459)
Deduct: Stock-based employee compensation expense if SFAS No. 123 had been applied to all grants	(13,310,256)	(6,897,933)	(19,298,093)
Pro forma net income (loss)	$(17,381,263)	$15,079,947	$(27,519,422)
Net income (loss) per share			
Basic—as reported	$ (0.24)	$ 1.13	$ (0.41)
Basic—pro forma	$ (0.96)	$ 0.79	$ (1.38)
Diluted—as reported	$ (0.24)	$ 1.04	$ (0.41)
Diluted—pro forma	$ (0.96)	$ 0.73	$ (1.38)

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 through June 30, 2004 and a trinomial lattice option-pricing fair value model thereafter. The following weighted-average assumptions were used:

	Year Ended June 30,		
	2003	2004	2005
Dividend yield	0.00%	0.00%	0.00%
Expected volatility	80%	78%	76%
Risk-free interest rate	2.8%	3.7%	4.0%
Expected life of the option term (in years)	6.3	5.9	5.4

On March 7, 2005, the Compensation Committee (the Committee) of the Company's Board of Directors approved the acceleration of vesting of "underwater" unvested stock options held by certain current employees, including executive officers. The Committee and the independent members of the Company's Board of Directors imposed restrictions on the stock option awards granted to executive officers of the Company, which restrict the ability of each such executive officer to sell any shares underlying any such stock option award until the earlier of (1) the original vesting date applicable to such shares (or any portion thereof) underlying such stock option award or (2) the executive officer's termination of employment with the Company, death or disability. Stock options held by non-employee directors were not included in such acceleration. A stock option was considered "underwater" if the option exercise price was greater than or equal to $32.35 per share. As such, the Company fully vested options to purchase 622,202 shares of the Company's Common Stock. The Company took this action primarily to avoid recognizing compensation cost in future financial statements when SFAS No. 123 (revised 2004) ("SFAS No. 123(R)") becomes effective, which will be the first quarter of the Company's 2006 fiscal year.

For pro forma disclosure requirements set forth above under SFAS No. 123, during the period ended June 30, 2005, the Company recognized $8.5 million of additional stock-based compensation for all options for which vesting was accelerated.

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 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.

RECENT ACCOUNTING PRONOUNCEMENTS

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123(R), "Share-Based Payment," which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes Accounting Pronouncement Bulletin No. 25, and amends SFAS No. 95, "Statement of Cash Flows." Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The Company is required to adopt SFAS No. 123(R) on July 1, 2005.

As permitted by SFAS No. 123, the Company currently accounts for share-based payments to employees using APB No. 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have a significant impact on the Company's statements of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described above in the disclosure of pro forma net income (loss) and earnings per share. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. The requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

In December 2004 the FASB also issued SFAS No. 151, "Inventory Costs." SFAS No. 151 requires abnormal amounts of inventory costs related to idle facility, freight handling and wasted material expenses to be recognized as current period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The standard is effective for fiscal years beginning after June 15, 2005. The Company believes the adoption of SFAS No. 151 will not have a material impact on its consolidated financial statements.

RECLASSIFICATIONS

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

3. Other Balance Sheet Information

The following tables provide details of selected balance sheet items:

INVENTORIES

	June 30,	
	2004	2005
Finished goods	$ 5,516,411	$ 4,642,294
Work in process	3,668,683	3,343,499
Raw materials	1,207,415	1,187,021
	10,392,509	9,172,814
Inventory reserve	(2,282,522)	(1,975,426)
	$ 8,109,987	$ 7,197,388

PROPERTY AND EQUIPMENT

	June 30,	
	2004	2005
Furniture, fixtures and office equipment	$ 3,348,037	$ 4,375,526
Machinery and equipment	4,700,011	4,986,474
Customer-use assets	9,998,546	9,665,519
Construction in-process	—	1,694,687
Leasehold improvements	2,005,455	2,798,999
	20,052,049	23,521,205
Accumulated depreciation and amortization	(10,490,255)	(13,417,160)
	$ 9,561,794	$ 10,104,045

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

	June 30, 2005			
AVAILABLE-FOR-SALE	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury and agencies	$22,190,931	$1,287	$(51,894)	$22,140,324
Corporate debt securities	8,187,225	—	(35,128)	8,152,097
Total Short-term investments	$30,378,156	$1,287	$(87,022)	$30,292,421

	June 30, 2004			
AVAILABLE-FOR-SALE	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated 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

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 Sheets at fair value.

The following table summarizes the maturities of the Company's Short-term investments at June 30, 2005:

MATURITY	Amortized Cost	Estimated Fair Value
Less than one year	$25,086,923	$25,003,003
Due in one to two years	5,291,233	5,289,418
	$30,378,156	$30,292,421

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,		
	2003	2004	2005
Gross proceeds	$5,410,773	$89,827,194	$30,511,560
Realized gains	640	—	2,786
Realized losses	(32)	(19)	(123)

ACCOUNTS PAYABLE

	June 30,	
	2004	2005
Trade payables	$4,261,514	$5,934,351
Other	1,162,114	1,872,965
	$5,423,628	$7,807,316

ACCRUED EXPENSES

	June 30,	
	2004	2005
Accrued expenses	$3,771,141	$ 4,496,460
Georgetown settlement	—	7,500,000
	$3,771,141	$11,996,460

4. Long-term Debt

The Company has 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. 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 and interest 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 to distribute the Company's HPV and chlamydia and gonorrhea products under a prior distribution agreement, the Company repurchased equipment it sold to Abbott Laboratories ("Abbott"). In order to satisfy this obligation, the Company issued a promissory note to Abbott for $4,033,904. The note bore interest at 7% per annum and the Company made quarterly installment payments of $336,159 which commenced on July 1, 2002. The Company paid off the note in its entirety on September 29, 2004.

In January 2003, as part of the repurchase of certain equipment from Roche Molecular Systems, Inc. ("Roche") 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 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, 2005, future minimum principal payments on all long-term debt obligations are as follows:

Fiscal 2006	$116,036
2007	118,007
2008	118,800
2009	120,020
2010	214,797
Thereafter	—
	$687,660

5. Income Taxes

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

	Year Ended June 30,		
	2003	2004	2005
Current:			
Federal	$ —	$ —	$ —
State	—	397,780	—
Foreign	223,465	175,804	360,520
Total current	223,465	573,584	360,520
Deferred:			
Federal	—	(12,832,429)	(2,636,522)
State	—	(2,066,102)	(297,673)
Foreign	—	—	—
Total deferred	—	(14,898,531)	(2,934,195)
Total provision for (benefit from) income taxes	$223,465	$(14,324,947)	$(2,573,675)

The Company recognized an income tax benefit of $14,324,947 and $2,573,675 for the year ended June 30, 2004 and 2005, respectively. For the year ended June 30, 2004, the Company revised its estimate of the valuation allowance previously established for the Company's deferred tax asset, resulting in a $14,898,531 income tax benefit. For the year ended June 30, 2005, the Company recognized an additional $2,934,195 income tax benefit for current year created U.S. net operating losses, other than net operating losses related to the exercise of stock options, and other deferred tax adjustments that are not subject to a valuation allowance.

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. The Company has not recorded deferred income taxes on the undistributed earnings of its foreign subsidiaries because the Company intends to indefinitely reinvest such earnings.

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

	Year Ended June 30,		
	2003	2004	2005
United States	$ 5,635,918	$ 21,545,679	$ (7,414,728)
Foreign	(9,735,964)	(14,328,598)	(3,325,817)
	$(4,100,046)	$ 7,217,081	$(10,740,545)

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,		
	2003	2004	2005
Tax (benefit) expense at statutory rates	$(1,394,000)	$ 2,472,152	$(3,759,190)
Effect of:			
State income tax, net	129,000	685,712	(193,832)
Foreign tax	223,465	175,804	(278,996)
Stock options	(708,000)	—	—
Tax rate adjustments	—	—	(1,831,081)
Net operating losses and tax credits	—	—	791,872
Permanent and other differences	(466,000)	571,176	750,782
Change in valuation allowance	2,439,000	(18,229,791)	1,946,770
Provision for (benefit from) income taxes	$ 223,465	$(14,324,947)	$(2,573,675)

For the year ended June 30, 2004, the change in the valuation allowance includes the partial reversal of the deferred tax valuation allowance of $14,898,531 discussed below. For the year ended June 30, 2005, the Company recognized a $4,282,991 foreign pre-tax loss from its European operations that did not generate an income tax benefit due to full valuation allowances booked against foreign deferred tax assets. The fiscal 2005 tax rate adjustment reflects increases, as compared to fiscal 2004, in U.S. federal income tax rate from 34% to 35% and in U.S. state gross income tax rate from 6% to 6.75%. Fiscal 2005 net operating losses and tax credits reflect impact of expired net operating losses and research tax credits and new research tax credits

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

	June 30,	
	2004	2005
Net operating loss carryforwards	$ 43,977,001	$ 51,941,410
Research and development credits	2,808,099	3,048,306
Fixed assets and intangibles	611,859	899,577
Reserves	1,593,161	1,359,687
Patent litigation settlement	—	2,954,063
Alternative minimum tax credit	41,920	41,920
Other	2,389,122	2,422,471
Deferred tax assets	51,421,162	62,667,434
Valuation allowance	(36,643,480)	(44,868,478)
	$ 14,777,682	$ 17,798,956

At June 30, 2005, the Company had U.S. tax net operating loss carryforwards for income tax purposes of $113,394,297. For June 30, 2005, the Company had $92,719,891 of the net operating loss carryforwards attributable to exercised stock options, the benefit of which, if realized, will increase additional paid-in capital. At June 30, 2005 the Company had foreign tax net operating loss carryforwards for income tax purposes of $22,181,359. At June 30, 2005, the Company also had U.S. research tax credit carryforwards of $3,048,306. The Company's U.S. net operating loss carryforwards and research tax credits expire, if unused, in various years from fiscal 2006 through 2025. Depending on the applicable foreign tax jurisdiction, the Company's foreign net operating loss carryforwards expire in certain jurisdictions, if unused, in various years starting in 2011; in several foreign tax jurisdictions the Company's foreign net operating losses can be carried forward indefinitely under current tax law.

Realization of total deferred tax assets is contingent upon the generation of future taxable income. Prior to fiscal 2004, the Company had experienced significant operating losses and operated in an industry subject to rapid technological change. Therefore, the Company's entire deferred tax assets were fully reserved with a valuation allowance prior to fiscal 2004. For the year ended June 30, 2004, the Company revised its estimate of the valuation allowance previously established for the Company's deferred tax asset, resulting in a $14,898,531 income tax benefit. For the year ended June 30, 2005, the Company recognized an additional $2,934,195 income tax benefit for current year created U.S. net operating losses, other than net operating losses related to the exercise of stock options, and other deferred tax adjustments that are not subject to a valuation allowance. Due to the uncertainty of realization of certain tax benefits, the Company has retained a portion of the valuation allowance for the net operating loss carryforwards that are related to the exercise of stock options as well as other U.S. net operating losses and U.S. research tax credits that are expected to expire unused. The Company has also retained a full valuation allowance for its foreign net operating losses. A significant portion of the remaining U.S. 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 remaining valuation allowance, if released, will be reflected as an increase to book income and will 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 recent historical financial trends and 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.

In 1991, the Company experienced a change in ownership as defined under Section 382 of the Internal Revenue Code, which caused the utilization of pre-change losses and credits to be limited. In fiscal 2005, all remaining 1991 pre-change losses and credits expired unused. The timing and manner in which the Company may utilize net operating loss carryforwards, U.S. research credit carryforwards, and U.S. alternative minimum tax credit carryforwards in any year, or in total, may be limited by Section 382 should an ownership change be determined to have occurred.

6. Stockholders' Equity

COMMON STOCK

Under the Roche Distribution Contract as discussed in Note 7, 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:

	Year Ended June 30,		
	2003	2004	2005
Numerator:			
Net income (loss)	$ (4,323,511)	$21,542,028	$ (8,166,870)
Denominator:			
Weighted average shares outstanding—Basic	18,135,689	19,144,021	19,964,800
Dilutive securities—stock options	—	1,662,057	—
Weighted average shares outstanding—Diluted	18,135,689	20,806,078	19,964,800
Basic net income (loss) per share	$ (0.24)	$ 1.13	$ (0.41)
Diluted net income (loss) per share	$ (0.24)	$ 1.04	$ (0.41)

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, 2003 and 2005 were included in the computation of diluted net loss per share because the effect 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, 2005, 1,498,233 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, 1,213,733 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,					
	2003		2004		2005	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of year	3,265,862	$20.62	4,051,013	$17.95	3,234,018	$23.74
Options granted	1,096,000	8.88	888,200	31.91	662,750	29.95
Options exercised	(209,623)	9.93	(1,558,710)	13.41	(153,335)	9.99
Options canceled or expired	(101,226)	22.64	(146,485)	23.12	(225,553)	28.44
Outstanding at end of year	4,051,013	17.95	3,234,018	23.74	3,517,880	25.22
Options exercisable at year-end	2,119,687	16.90	1,322,233	25.00	2,607,335	27.35

The following table summarizes information about stock options outstanding at June 30, 2005:

	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	688,806	6.4	$ 7.33	396,396	$ 7.55
$10.01–$20.00	339,108	5.9	14.61	203,178	13.61
$20.01–$30.00	845,683	7.4	26.30	398,578	26.01
$30.01–$40.00	1,593,283	6.4	33.95	1,558,183	33.88
$40.01–$47.63	51,000	7.7	46.97	51,000	46.97
	3,517,880	6.6	25.22	2,607,335	27.35

The weighted-average fair values of the options granted during the years ended June 30, 2003, 2004 and 2005 were $6.50, $15.94 and $17.81, respectively.

The Company issued 25,000 stock options to a non-employee during the year ended June 30, 2003. These stock options had a vesting period of 30 months. The fair value of these stock options was recorded as deferred compensation and was amortized over the performance period. Under variable plan accounting, the value of the unvested stock options was 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 options to extend the term for a five-year period 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 eight 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, 2005:

2006	$ 3,566,728
2007	3,456,901
2008	3,227,884
2009	3,165,400
2010	1,630,055
Thereafter	158,258
	$15,205,226

Rent expense under these leases was $3,174,602, $3,448,493, and $4,040,397 for the years ended June 30, 2003, 2004 and 2005, respectively.

ROYALTY AND TECHNOLOGY EXPENSES

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, 2003, 2004 and 2005, total royalties amounted to $2,813,556, $1,704,837 and $5,393,343, respectively.

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. On October 13, 2004, the Company executed a Settlement and License Agreement with Enzo Biochem, Inc. and its subsidiary Enzo Life Sciences, Inc. (formerly known as Enzo Diagnostics, Inc.) (collectively, "Enzo"), to settle patent litigation claims then pending in the United States District Court for the District of Delaware.

Under the Settlement and License Agreement (the "Enzo Agreement"), Digene received an irrevocable, non-exclusive, royalty-bearing worldwide license under identified Enzo patents. Digene made an initial payment to Enzo of $16.0 million, of which $2.0 million can be used to offset future royalty payments under the terms of the Enzo Agreement, resulting in $14.0 million in patent litigation settlement expense. Digene will also pay Enzo royalties on future net sales of products covered by the license grant, which royalties will be at least $2.5 million for the first annual period, beginning October 1, 2004 and ending September 30, 2005, and at least $3.5 million for each of the next four annual periods under the Enzo Agreement. Digene is obligated to make such guaranteed minimum payments in such first five annual periods. Digene's obligation to make royalty payments will end on April 24, 2018, unless earlier terminated in accordance with the terms of the Enzo Agreement.

In July 2001, Institut Pasteur notified the Company that Institut Pasteur was granted a new U.S. patent concerning the HBV genome and requested information from Digene regarding products that may use the technology described in such new patent. On January 4, 2005, the Company made a payment for additional royalty and technology expense of $750,000, which was accrued at December 31, 2004, relating to terms agreed to on October 14, 2004 with Institut Pasteur with respect to a non-exclusive license to Institut Pasteur's intellectual property concerning the HBV genome.

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. On July 12, 2005, the Company executed a Settlement and License Agreement with Georgetown University (the "Georgetown Agreement") to settle litigation then pending in the United States District Court for the District of Columbia. Under the Georgetown Agreement, the Company received irrevocable, world-wide, exclusive, royalty-bearing licenses with the right to grant sublicenses under identified Georgetown patents. Additionally, the Georgetown Agreement contained a mutual release for all past claims. As of June 30, 2005, the Company recorded its $7,500,000 obligation to Georgetown. In July 2005, the Company made an initial payment to Georgetown University of $3,750,000, and will make a second payment to Georgetown University of $3,750,000 no later than October 15, 2005. The Company will also pay Georgetown University royalties on future net sales of products covered by the license grant.

REPURCHASE OF EQUIPMENT UNDER PRIOR MARKETING AND DISTRIBUTION AGREEMENTS

On April 29, 2001, the Company entered into an agreement (the "Roche Distribution Contract") with 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.

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.

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.

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.

CO-PROMOTION AGREEMENT

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 U.S. Food and Drug Administration 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 year ended June 30, 2003, the Company recorded expenses of approximately $2.3 million, related to payments due to Cytyc for these co-promotion activities. For the years ended June 30, 2004 and 2005, 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.

8. Warranties

The Company reserves approximately 2% of product sales for its standard warranty obligations. The Company also offers its customers extended warranties on its equipment. The revenue from these extended warranties is deferred and is recognized evenly over the period of the extended warranty. Changes in the Company's standard warranty reserve are as follows:

	For the Year Ended June 30,	
	2004	2005
Balance, beginning of period	$ 633,430	$ 896,626
Warranties issued during the period	1,776,057	2,274,912
Changes in liability for pre-existing warranties during the period, including expirations	(1,512,861)	(2,034,289)
Balance, end of period	$ 896,626	$ 1,137,249

9. Retirement Plan

The Company sponsors a 401(k) Profit Sharing Plan (the "Plan"), which covers all employees. Employees may contribute to the Plan beginning the first of the month after hire. 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, 2003 or 2004. In January 2005, the Company contributed approximately $122,000 to the Plan relating to the calendar year 2004 employee contributions. As of June 30, 2004 and 2005, the Company recorded an accrual of approximately $50,000 and $75,000, respectively, for contributions to be made in the next fiscal year.

10. Significant Customers and Geographic Information

For the year ended June 30, 2003, two customers comprised 18% and 10% of total revenues, respectively. For the year ended June 30, 2004, two customers generated 17% and 10% of total revenue, respectively. For the year ended June 30, 2005, two customers generated 20% and 12% of total revenue, respectively. As of June 30, 2004 and 2005, the Company recorded receivable balances of approximately $4,186,000 and $5,399,000, 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:

	2003		2004		2005	
	Assets	Revenues	Assets	Revenues	Assets	Revenues
North America	$50,845,853	$46,279,902	$ 92,526,699	$67,169,751	$ 92,682,912	$ 88,577,142
Europe	11,310,693	11,174,822	9,789,249	15,841,533	12,690,511	18,221,949
Latin America	1,170,898	2,703,297	928,048	3,292,641	1,464,285	3,973,103
Pacific Rim	47,706	2,943,875	26,252	3,856,643	7,722	4,369,409
	$63,375,150	$63,101,896	$103,270,248	$90,160,568	$106,845,430	$115,141,603

11. 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
2005				
Revenues	$26,211	$26,953	$29,667	$32,311
Net income (loss)	$ (6,273)	$ 304	$ 1,565	$ (3,763)
Basic net income (loss) per share	$ (0.32)	$ 0.02	$ 0.08	$ (0.19)
Diluted net income per share	$ (0.32)	$ 0.01	$ 0.08	$ (0.19)
2004				
Revenues	$19,618	$21,114	$23,565	$25,863
Net income (loss)	$ 655	$ 948	$ 2,490	$17,448
Basic net income (loss) per share	$ 0.04	$ 0.05	$ 0.13	$ 0.88
Diluted net income (loss) per share	$ 0.03	$ 0.05	$ 0.12	$ 0.83

The sum of basic and diluted net income (loss) per share for the four quarters in each of fiscal 2005 and 2004 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 of fiscal 2004 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 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, 2004 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Digene Corporation at June 30, 2004 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Digene Corporation's internal control over financial reporting as of June 30, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated August 12, 2005 expressed an unqualified opinion thereon.

Ernst & Young LLP

McLean, Virginia
August 12, 2005

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). There are inherent limitations in the effectiveness of any internal controls over financial reporting, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of June 30, 2005 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management's assessment of the effectiveness of our internal control over financial reporting as of June 30, 2005 has been audited by Ernst & Young LLP, independent registered public accounting firm, as stated in their report which is included below.

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

THE BOARD OF DIRECTORS AND STOCKHOLDERS
DIGENE CORPORATION

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting that Digene Corporation maintained effective internal control over financial reporting as of June 30 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Digene Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Digene Corporation maintained effective internal control over financial reporting as of June 30, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Digene Corporation maintained, in all material respects, effective internal control over financial reporting as of Digene Corporation, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Digene Corporation as of June 30, 2004 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2005 of Digene Corporation and our report dated August 12, 2005 expressed an unqualified opinion thereon.

Ernst & Young LLP

McLean, Virginia
August 12, 2005

Reconciliation of GAAP Financial Information to Non-GAAP Financial Information

To supplement our consolidated financial statements presented in accordance with generally accepted accounting principles (GAAP), Digene uses non-GAAP measures of certain components of financial performance, including income before income taxes, net income and earnings per share, which are adjusted from results based on GAAP. Although "as adjusted" financial measures are non-GAAP financial measures, we believe that the presentation of "as adjusted" financial measures calculated to exclude "special items" are useful adjuncts to the GAAP "as reported" financial measures. "Special items" consist of:

- an adjustment to reflect a 38% effective tax rate for each of FY '05 and FY '04
- and for FY '05, "special items" also exclude a $7.5 million patent litigation settlement expense accrual we made under our Settlement and License Agreement with Georgetown University, and a $14 million patent litigation settlement expense from payments we made under our Settlement and License Agreement with Enzo Biochem, Inc.

The presentation of "as adjusted" financial measures in each reported period reflects adjustments for the "special items" detailed above.

These non-GAAP measures are provided to enhance investors' overall understanding of Digene's current financial performance and its prospects for the future. These measures should be considered in addition to results prepared in accordance with generally accepted accounting principles, but should not be considered a substitute for, or superior to, GAAP results. The following table shows the reconciliation of non-GAAP measures included in this annual report to the most directly comparable GAAP measure.

Reconciliation of GAAP Financial Information to Non-GAAP Financial Information Twelve Months Ended June 30, 2005 and June 30, 2004

(in thousands, except net income (loss) per share and shares)

	Twelve Months Ended June 30, 2005	Twelve Months Ended June 30, 2004
INCOME (LOSS) BEFORE INCOME TAX		
Income (loss) before income tax—as reported	$ (10,741)	$ 7,217
Special item(s):		
Exclude Georgetown University patent litigation settlement expense	7,500	—
Exclude Enzo Biochem Inc. patent litigation settlement expense	14,000	—
Income (loss) before income tax—as adjusted	$ 10,759	$ 7,217
NET INCOME (LOSS)		
Net income (loss)—as reported	$ (8,167)	$ 21,542
Special item(s):		
Adjustment to reflect 38% tax rate	(6,662)	(17,067)
Exclude Georgetown University patent litigation settlement expense	7,500	—
Exclude Enzo Biochem Inc. patent litigation settlement expense	14,000	—
Net income—as adjusted	$ 6,671	$ 4,475
DILUTED NET INCOME (LOSS) PER SHARE		
Diluted net income (loss) per share—as reported	$ (0.41)	$ 1.04
Special item(s):		
Adjustment to reflect 38% tax rate	(0.33)	(0.82)
Exclude Georgetown University patent litigation settlement expense	0.38	—
Exclude Enzo Biochem Inc. patent litigation settlement expense	0.70	—
Adjustment for increase in diluted shares outstanding—as adjusted	(0.02)	—
Diluted net income (loss) per share—as adjusted	$ 0.32	$ 0.22
Diluted weighted average shares outstanding—as reported	19,964,800	20,806,078
Special item(s):		
Increase in shares due to net loss—as reported versus net income—as adjusted	695,585	—
Diluted weighted average shares outstanding—as adjusted	20,660,385	20,806,078

Corporate Information

Corporate Headquarters

Digene Corporation
1201 Clopper Road
Gaithersburg, Maryland 20878
Phone: 800-DIGENE-1
Fax: 301-944-7121
Email: inforeq@digene.com
www.digene.com

DIGENE BRAZIL
Rua Dr. Bacelar, 333
Sao Paulo SP 04026-001
Brazil

DIGENE DEUTSCHLAND GMBH
Philipp-Reis-Str. 14
D-63303 Dreieich
Germany

DIGENE FRANCE SAS
1, rue de la Pepiniere
75008 Paris
France

DIGENE ITALIA SRL
Piazza Santa Francesca Romana 3
20129 Milano
Italy

DIGENE DIAGNOSTICS, S.L.
Edificio Alba Rosa de Lima, 1
Las Matas. Madrid
28290
Spain

DIGENE SWITZERLAND SARL
P.O. Box 1871
ICC-Route de Pre-Bois 20
1215 Geneva 15
Switzerland

DIGENE UK LTD
Unit 2.3
Shepherds Central
Charecroft Way
London W14 0EH
United Kingdom

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:

Charles M. Fleischman
President, Chief Operating Officer and Chief Financial Officer
Digene Corporation
1201 Clopper Road
Gaithersburg, Maryland 20878

Independent Auditors

Ernst & Young LLP
8484 Westpark Drive
McLean, Virginia 22102

Legal Counsel

Ballard Spahr Andrews & Ingersoll, LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103

Transfer Agent and Registrar

StockTrans, Inc.
44 West Lancaster Avenue
Ardmore, Pennsylvania 19003

Annual Meeting

October 26, 2005

Investor Relations

Financial Dynamics
88 Pine Street, 32nd Floor
New York, New York 10005
Phone: 212-850-5600

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:

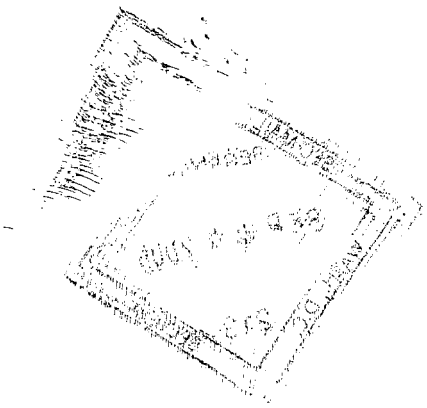
Fiscal 2006 (through September 8, 2005)	High	Low
First quarter	$32.14	$27.25
Fiscal 2005		
Fourth quarter	$29.66	$16.94
Third quarter	26.82	20.46
Second quarter	27.45	18.50
First quarter	36.25	19.88
Fiscal 2004		
Fourth quarter	$40.86	$33.02
Third quarter	48.50	29.33
Second quarter	46.24	32.59
First quarter	49.45	25.71

On September 8, 2005, the closing sale price for the Common Stock, as reported by the Nasdaq National Market, was $29.98. As of September 8, 2005, Digene's Common Stock was held by 148 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, DNAwithPap, hc_2 High-Risk HPV DNA Test and Rapid Capture are registered trademarks, and UCM, DNAPap and the HPV test logo are trademarks of Digene Corporation. ThinPrep and PreservCyt are registered trademarks of Cytyc Corporation. SurePath is a trademark of TriPath Imaging, Inc.



DIGENE

1201 Clopper Road, Gaithersburg, MD 20878
www.digene.com