

QIAGEN NV  
Form 20-F  
March 20, 2008  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 20-F**

.. REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
or

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2007

or

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from to

or

.. SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Date of event requiring this shell company report

**Commission File Number 0-28564**

**QIAGEN N.V.**

(Exact name of Registrant as specified in its charter)

n/a

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(Translation of Registrant's name in English)

The Netherlands

(Jurisdiction of incorporation or organization)

Spoorstraat 50

5911 KJ Venlo

The Netherlands

011-31-77-320-8400

(Address of principal executive offices)

Roland Sackers, Tel: (240) 686-7700, Fax: (240) 686-7772

QIAGEN N.V., 19300 Germantown Rd. Germantown, Maryland 20874

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class:

Name of each exchange on which registered:

Common Shares, par value EUR 0.01 per share

NASDAQ Stock Market LLC

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

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

The number of outstanding Common Shares as of December 31, 2007 was 195,335,076.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.  Yes  No

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Note: Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections. Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark which financial statement item the registrant has elected to follow.  Item 17  Item 18

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If  Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17

Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

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Unless the context otherwise requires, references herein to we, us, our, the Company or to QIAGEN are to QIAGEN N.V. and its consolidated subsidiaries.

Our name together with our logo is registered as a trademark in the United States and a number of other countries: QIAGEN®. Other trademarks registered in the United States and in other countries include, inter alia: QIAexpress®, QIAwell®, QIAEX®, QIAprep®, QIAamp®, QIAquick®, Oligotex®, RNeasy®, BIOROBOT®, ENDOFREE®, R.E.A.L.®, PolyFect®, SuperFect®, DNeasy®, UltraFect®, TurboFilter®, HotStarTaq®, EFFECTENE®, QIA®, DyeEx®, Omniscript®, Sensiscript®, HiSpeed®, Targetene®, TransMessenger®, MagAttract®, DirectPrep®, InhibitEX®, DoubleTag®, QuantiScript®, UltraSens®, pAlliance®, MinElute®, EverGene®, ProofStart®, FlexiGene®, QuantiTect®, DNAprotect®, RNAprotect® and LiquiChip®, LabelStar®, EasyXpress® RNAiFect® BioSprint®, TISSUERUPTOR®, THE SAMPLE & ASSAY COMPANY®, QIAGEN THE SAMPLE & ASSAY COMPANY®, QIAGEN SAMPLE & ASSAY TECHNOLOGIES®, QIACUBE®, QIASYMPHONY®, ARRAY IN A DAY®, DIGENE®, DIGENE design®, DNA WITH PAP®, HC EXPRESSARRAY®, HC2 HIGH-RISK HPV DNA TEST®, HYBRID CAPTURE®, RAPID CAPTURE®, SHARP SIGNAL®, AND VIRATYPE®.

Registered trademarks in countries outside of the United States include: QIABRANE®, ProofTaq®, Easylabel®, Qproteome®, FastLane®, EpiTect®.

In 2007, 23 trademark applications were filed in Germany, Countries of the European Community, Japan, Canada and the United States of America such as QIAPLEX®, STOP RNASE®, TopTaq®, Q-Solution®, HIPERFECT®, GENESOLUTION®, FLEXITUBE®, and ENSEMBLE®. In addition, applications have been filed prior to 2007 in various jurisdictions for CAPTURA HYBRIDA, DNA PAP, and UCM.

This Annual Report on Form 20-F may also contain trade names or trademarks of companies other than QIAGEN.

## **EXCHANGE RATES**

QIAGEN publishes its financial statements in U.S. dollars. In this Annual Report on Form 20-F, references to dollars or \$ are to U.S. dollars, and references to EUR or the euro are to the European Monetary Union euro. Except as otherwise stated herein, all monetary amounts in this Annual Report on Form 20-F have been presented in U.S. dollars.

The exchange rate used for the euro was the noon buying rate of the euro in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Board of New York. This rate at March 19, 2008, was \$1.5642 per EUR 1.

For information regarding the effects of currency fluctuations on our results, see Item 5 Operating and Financial Review and Prospects.

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Not applicable.

**Item 2. Offer Statistics and Expected Timetables**

Not applicable.

**Item 3. Key Information**

The selected consolidated financial data below should be read in conjunction with *Operating and Financial Review and Prospects* and the Consolidated Financial Statements, notes thereto and other financial information included elsewhere in this Annual Report on Form 20-F. The selected consolidated statements of income data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data at December 31, 2007 and 2006 are derived from the Consolidated Financial Statements of QIAGEN which have been audited by an independent registered public accounting firm, and are included herein. The selected consolidated statements of income data presented for the years ended December 31, 2004 and 2003, and the consolidated balance sheet data as of December 31, 2005, 2004 and 2003, is derived from audited consolidated financial statements not included herein.

**Selected Financial Data**

*The information below should be read in conjunction with the consolidated financial statements (and notes thereto) and Operating and Financial Review and Prospects.*

	<b>Years ended December 31,</b>				
	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Consolidated Statement of Income Data:</b>					
<b>(amounts in thousands, except per share data)</b>					
Net sales	<b>\$ 649,774</b>	\$ 465,778	\$ 398,395	\$ 380,629	\$ 351,404
Cost of sales	<b>189,773</b>	139,122	122,755	125,658	118,786
Cost of sales acquisition and restructuring related	<b>2,839</b>	2,046	439	1,454	3,618
Cost of sales acquisition related intangible amortization	<b>23,615</b>	6,135	3,319	1,416	1,096
Gross profit	<b>433,547</b>	318,475	271,882	252,101	227,904
<b>Operating Expenses:</b>					
Research and development	<b>64,935</b>	41,560	35,780	34,351	31,068
Sales and marketing	<b>164,690</b>	115,942	94,312	87,506	83,005
General and administrative	<b>71,932</b>	48,574	40,123	41,715	41,894
Purchased in-process research and development	<b>25,900</b>	2,200	3,239		
Acquisition, integration and related costs	<b>14,708</b>	6,061	3,213	572	
Acquisition related intangible amortization	<b>7,711</b>	2,085	378		
Relocation and restructuring costs	<b>538</b>	1,452		3,817	3,048
Total operating expenses	<b>350,414</b>	217,874	177,045	167,961	159,015
Income from operations	<b>83,133</b>	100,601	94,837	84,140	68,889
Other income (expense), net	<b>(7,407)</b>	5,467	2,427	(11,453)	(1,634)

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Income before provision for income taxes and minority interest	<b>75,726</b>	106,068	97,264	72,687	67,255
Provision for income taxes	<b>25,555</b>	35,529	35,039	23,982	24,405
Minority interest	<b>49</b>				
<b>Net income</b>	<b>\$ 50,122</b>	\$ 70,539	\$ 62,225	\$ 48,705	\$ 42,850
Basic net income per Common Share(1)	<b>\$ 0.30</b>	\$ 0.47	\$ 0.42	\$ 0.33	\$ 0.29
<b>Diluted net income per Common Share(1)</b>	<b>\$ 0.28</b>	\$ 0.46	\$ 0.41	\$ 0.33	\$ 0.29
Weighted average number of Common Shares used to compute basic net income per Common Share	<b>168,457</b>	149,504	147,837	146,658	145,832
Weighted average number of Common Shares used to compute diluted net income per Common Share	<b>175,959</b>	153,517	150,172	148,519	147,173

(1) See Note 3 of the Notes to Consolidated Financial Statements for the computation of the weighted average number of Common Shares.

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	As of December 31,				
	2007	2006	2005	2004	2003
<b>Consolidated Balance Sheet Data:</b>					
<b>(amounts in thousands)</b>					
Cash and cash equivalents	\$ 347,320	\$ 430,357	\$ 191,700	\$ 196,375	\$ 98,993
Working capital	\$ 482,215	\$ 566,660	\$ 278,586	\$ 299,029	\$ 163,583
Total assets	\$ 2,775,174	\$ 1,212,012	\$ 765,298	\$ 714,599	\$ 551,930
Total long-term liabilities, including current portion	\$ 1,220,084	\$ 536,738	\$ 230,086	\$ 234,138	\$ 131,095
Total shareholders' equity	\$ 1,391,575	\$ 566,165	\$ 450,457	\$ 400,376	\$ 334,786
Common Shares	\$ 2,175	\$ 1,535	\$ 1,513	\$ 1,495	\$ 1,485
Shares outstanding	195,335	150,168	148,456	147,020	146,218

**Risk Factors****Note regarding Forward-Looking Statements and Risk Factors**

Our future operating results may be affected by various risk factors, many of which are beyond our control. Certain of the statements included in this Annual Report and the documents incorporated herein by reference may be forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended, including statements regarding potential future net sales, gross profit, net income and liquidity. These statements can be identified by the use of forward-looking terminology such as believe, hope, plan, intend, seek, may, will, could, should, would, expect, anticipate, estimate, words. Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives, and other forward-looking statements. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. We caution investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors. Factors which could cause such results to differ materially from those described in the forward-looking statements include those set forth in the risk factors below. As a result, our future development efforts involve a high degree of risk. When considering forward-looking statements, you should keep in mind that the risk factors could cause our actual results to differ significantly from those contained in any forward-looking statement.

**Risks Related to Our Business****An inability to manage our growth, manage the expansion of our operations, or successfully integrate acquired businesses could adversely affect our business.**

Our business has grown rapidly, with total net revenues increasing from \$263.8 million in 2001 to \$649.8 million in 2007. In 2007, we completed the construction of a new logistics facility in Germany. Additionally, we have made several acquisitions in the last few years, including our acquisition of Digene Corporation in July 2007, and may acquire additional businesses in the future. The successful integration of acquired businesses requires a significant effort and expense across all operational areas, including sales and marketing, research and development, manufacturing, finance and administration and information technologies.

Our earlier expansion of facilities in Maryland and Germany added production capacity and increased fixed costs. These higher fixed costs will continue to be a cost of production in the future, and until we more fully utilize the additional capacity of the facilities, our gross profit will be negatively impacted. We have also upgraded our operating and financial systems and expanded the geographic area of our operations, resulting in the hiring of new employees, as well as increased responsibility for both existing and new management personnel. The rapid expansion of our business and addition of new personnel may place a strain on our management and operational systems.



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Our future operating results will depend on the ability of our management to continue to implement and improve our research, product development, manufacturing, sales and marketing and customer support programs, enhance our operational and financial control systems, expand, train and manage our employee base, integrate acquired businesses, and effectively address new issues related to our growth as they arise. There can be no assurance that we will be able to manage our recent or any future expansion or acquisition successfully, and any inability to do so could have a material adverse effect on our results of operations.

### **Our acquisitions expose us to new risks, and we may not achieve the anticipated benefits of acquisitions of technologies and businesses.**

During the past several years we have acquired a number of companies, including our acquisition of Digene Corporation in July 2007, through which we have gained access to technologies and products that complement our internally developed product lines. In the future, we may acquire additional technologies, products or businesses to expand our existing and planned business. Acquisitions, including our acquisition of Digene, expose us to the addition of new operating and other risks including the risks associated with the:

assimilation of new technologies, operations, sites and personnel;

application for and achievement of regulatory approvals or other clearances;

diversion of resources from our existing business and technologies;

inability to generate revenues to offset associated acquisition costs;

inability to implement and maintain uniform standards and effective controls and procedures;

inability to maintain relationships with employees and customers as a result of any integration of new management personnel;

issuance of dilutive equity securities;

incurrence or assumption of debt;

additional expenses associated with future amortization or impairment of acquired intangible assets or potential businesses; or

assumption of liabilities or exposure to claims against acquired entities.

Our failure to address the above risks successfully in the future may prevent us from achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all.

### **Our continued growth is dependent on the development and success of new products.**

Rapid technological change and frequent new product introductions are typical in our markets. Our future success will depend in part on continuous, timely development and introduction of new products that address evolving market requirements. We believe successful new product introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product and are reluctant to switch thereafter. To the extent that we fail to introduce new and innovative products, we may lose market share to our competitors, which will be difficult or impossible to regain. An inability, for technological or other reasons, to successfully develop

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and introduce new products could reduce our growth rate or otherwise have an adverse effect on our business. In the past, we have experienced, and are likely to experience in the future, delays in the development and introduction of products. We cannot assure you that we will keep pace with the rapid rate of change in our markets or that our new products will adequately meet the requirements of the marketplace or achieve market acceptance. Some of the factors affecting market acceptance of new products include:

availability, quality and price relative to competitive products;

the timing of introduction of the new product relative to competitive products;

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scientists' opinions of the new products' utility;

citation of the new product in published research;

regulatory trends and approvals; and

general trends in life sciences research, applied markets and molecular diagnostics.

The expenses or losses associated with unsuccessful product development activities or lack of market acceptance of our new products could materially adversely affect our business, financial condition and results of operations.

**We depend on patents and proprietary rights that may fail to protect our business.**

Our success will depend to a large extent on our ability to develop proprietary products and technologies and to establish and protect our patent and trademark rights in these products and technologies. As of December 31, 2007, we owned 109 issued patents in the United States, 70 issued patents in Germany and 434 issued patents in other major industrialized countries. In addition, at December 31, 2007, we had 619 pending patent applications, and we intend to file applications for additional patents as our products and technologies are developed.

The patent positions of technology-based companies, including QIAGEN, involve complex legal and factual questions and may be uncertain, and the laws governing the scope of patent coverage and the periods of enforceability of patent protection are subject to change. In addition, patent applications in the United States are maintained in secrecy until patents issue, and publication of discoveries in the scientific or patent literature tend to lag behind actual discoveries by several months. Therefore, no assurance can be given that patents will issue from any patent applications that we own or license or if patents do issue, that the claims allowed will be sufficiently broad to protect our technology. In addition, no assurance can be given that any issued patents that we own or license will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide us competitive advantages. Further, as issued patents expire, we may lose some competitive advantage as others develop competing products and as a result, we may lose revenue.

Although we have the only fully commercialized and FDA-approved test for the detection of the human Papillomavirus (HPV), a significant portion of our HPV-related intellectual property is in the public domain, subject to patents that will begin to expire in the next few years or are not licensed to us on a sole and exclusive basis. As a result, we believe other companies are developing or may develop HPV detection tests in the next few years.

Certain of our products incorporate patents and technologies that are licensed from third parties and for certain products, these in-licensed patents together with other patents provide us with a competitive advantage. These licenses impose various commercialization, sublicensing and other obligations on us. Our failure to comply with these requirements could result in the conversion of the applicable license from being exclusive to non-exclusive in nature or, in some cases, termination of the license and as a result we may lose some competitive advantage and experience a loss of revenue.

We also rely on trade secrets and proprietary know-how, which we seek to protect through confidentiality agreements with our employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors will provide meaningful protection for our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. There also can be no assurance that our trade secrets will not otherwise become known or be independently developed by competitors.

We currently engage in, and may continue to engage in, collaborations with academic researchers and institutions. There can be no assurance that under the terms of such collaborations, third parties will not acquire rights in certain inventions developed during the course of the performance of such collaborations.

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**Our concentration of a large amount of revenues in a single product and a small number of customers for that product increases our dependence on that product's success, our reliance on our relationship with each of those customers, and our reliance on a diversification strategy.**

Following our acquisition of Digene Corporation, we believe that revenue from sales of our HPV test product may represent as much as 20% of our total revenues. While the ultimate decision to order that test is made by the patient in consultation with her physician, the test is performed by reference laboratories. At present, sales to a limited number of reference laboratories account for substantially all of our revenues for that product. If there is a significant reduction in sales of this product that is not replaced by revenues from new products or customers or an increase in revenues from existing products or customers, then it will have a significant adverse impact on our earnings. Further, the cost of HPV testing is reimbursed to the reference laboratories by insurance providers and healthcare maintenance organizations. If these insurance companies decide to limit the availability of payments for our test to their members, it could have a significant adverse impact on our revenues. It is possible that our dependence on revenues from this product and those customers will continue in the future. If we fail to diversify our product line and customer base for this product, we may continue to be at risk that the loss or under-performance of a single product or customer may materially affect our earnings.

**Our sales of HPV products and our growth will also depend on continued increases in the acceptance of and the market for HPV screening by physicians and laboratories.**

Our sales of HPV products and our ability to increase sales of HPV products depend upon continued and increasing acceptance by physicians and laboratories of HPV screening as a necessary part of the standard of care for cervical cancer screening and, more specifically, of our HPV test products as a primary cervical cancer screening method, in conjunction with Pap tests, independent of Pap tests, and in conjunction with the implementation of HPV vaccinations. Pap tests have been the principal means of cervical cancer screening since the 1940s. Technological advances designed to improve quality control over sample collection and preservation and to reduce the Pap test's susceptibility to human error may increase physician reliance on the Pap test and solidify its market position as the most widely used screen for cervical cancer. Currently, approximately 60 million Pap tests are performed annually in the United States and we believe that 60 to 100 million are performed annually in the rest of the world.

HPV testing applies a new molecular-based technology and testing approach that is different from the cytology-based (reviewing cells under a microscope) approach of the Pap test. Significant resources are required to educate physicians and laboratories about the patient benefits that can result from using HPV test products in addition to the Pap test, and to assist laboratory customers in learning how to use our HPV test products. Using our HPV test products along with the Pap test for primary screening in the United States may be seen by some of these customers as adding unnecessary expense to the generally accepted cervical cancer screening methodology, and therefore, we frequently need to provide information to counteract this impression on a case-by-case basis. If we are not successful in executing our marketing strategies, we may not be able to maintain or continue to grow our market share for HPV testing.

Direct-to-consumer awareness marketing programs are used because a well educated female population will work with their health care providers to increase the use of the HPV Test. If we are not successful in continuing to execute this marketing program, we may not be able to maintain or continue to increase the sales of our HPV tests to the extent we desire.

We are working with physician and laboratory customers and with others to develop and establish the role HPV screening will play in addition to and in conjunction with HPV vaccination. If we are not successful in this endeavor, we may not be able to maintain or grow the market for HPV screening or maintain or increase our HPV test revenues.

Our products for the diagnosis of the presence of chlamydia and gonorrhea compete with other FDA-approved products that detect the presence of such infectious diseases. Our marketing activities focus on

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providing information regarding the accuracy and objective nature of these diagnostic tests, but such activities are time-consuming and expensive. We believe the best way to increase our revenues from these products is to educate laboratories and physicians about the ability to run such tests from the same patient sample collected for HPV testing. If we are not successful in executing our marketing strategy, we do not expect to significantly grow revenues from these products.

### **We are subject to risks associated with patent litigation.**

The biotechnology industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We are aware that patents have been applied for and/or issued to third parties claiming technologies for the separation and purification of nucleic acids that are closely related to those we use. From time to time we receive inquiries requesting confirmation that we do not infringe patents of third parties. We endeavor to follow developments in this field, and we do not believe that our technologies or products infringe any proprietary rights of third parties. However, there can be no assurance that third parties will not challenge our activities and, if so challenged, that we will prevail. In addition, the patent and proprietary rights of others could require that we alter our products or processes, pay licensing fees or cease certain activities, and there can be no assurance that we will be able to license any technologies that we may require on acceptable terms. In addition, litigation, including proceedings that may be declared by the U.S. Patent and Trademark Office or the International Trade Commission, may be necessary to respond to any assertions of infringement, enforce our patent rights and/or determine the scope and validity of our proprietary rights or those of third parties. Litigation could involve substantial cost, and there can be no assurance that we would prevail in any such proceedings.

### **Our ability to accurately forecast our results during each quarter may be negatively impacted by the fact that a substantial percentage of our sales may be recorded in the final weeks or days of the quarter.**

The markets we serve are characterized by a high percentage of purchase orders being received in the final few weeks or even days of each quarter. Although this varies from quarter to quarter, many customers make a large portion of their purchase decisions late in each fiscal quarter, as both their budgets and requirements for the coming quarter become clearer. As a result, even late in each fiscal quarter, we cannot predict with certainty whether our revenue forecasts for the quarter will be achieved. Historically, we have been able to rely on the overall pattern of customer purchase orders during prior periods to project with reasonable accuracy our anticipated sales for the current or coming quarters. However, if our customers' purchases during a quarter vary from historical patterns, our final quarterly results could deviate significantly from our projections. Consequently, our revenue forecasts for any given quarter may prove not to have been accurate. We may not have enough information as a result of such patterns to confirm or revise our sales projections during a quarter. If we fail to achieve our forecasted revenues for a particular quarter, our stock price could be adversely affected.

### **Our operating results may vary significantly from period to period.**

Our operating results may vary significantly from quarter to quarter and from year to year, depending on factors such as the level and timing of our customers' research and commercialization efforts, the timing of our customers' funding, the timing of our research and development and sales and marketing expenses, the introduction of new products by us or our competitors, competitive conditions, exchange rate fluctuations and general economic conditions. Our expense levels are based in part on our expectations as to future revenues. Consequently, revenues or profits may vary significantly from quarter to quarter or from year to year, and revenues and profits in any interim period will not necessarily be indicative of results in subsequent periods.

### **Competition could reduce sales.**

Our primary competition stems from traditional methods ( traditional or home-brew methods) that utilize widely available reagents and other chemicals to perform sample and assay processing steps. We are also aware that a significant number of laboratory organizations and other companies are developing and using

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internally developed, or home-brew, molecular tests such as HPV tests. These tests, although not approved by the FDA or similar non-U.S. regulatory authorities, do offer an alternative to our products that could limit the laboratory customer base for our product. The success of our business depends in part on the continued conversion of current users of such traditional methods to our sample and assay technologies and products. There can be no assurance, however, as to how quickly such conversion will occur.

We also have experienced, and expect to continue to experience, increasing competition in various segments of our business from companies providing competitive pre-analytical products and other products competitive with our own. The markets for certain of our products are very competitive and price sensitive. Other product suppliers have significant financial, operational, sales and marketing resources, and experience in research and development. These and other companies may have developed or could in the future develop new technologies that compete with our products or even render our products obsolete. If a competitor develops superior technology or cost-effective alternatives to our kits and other products, our business, operating results and financial condition could be materially adversely affected.

We believe that customers in the market for pre-analytical solutions and assay technologies display a significant amount of loyalty to their initial supplier of a particular product. Therefore, it may be difficult to generate sales to customers who have purchased products from competitors. To the extent we are unable to be the first to develop and supply new products, our competitive position may suffer.

### **Reduction in research and development budgets and government funding may result in reduced sales.**

Our customers include researchers at pharmaceutical and biotechnology companies, academic institutions and government and private laboratories. Fluctuations in the research and development budgets of these researchers and their organizations for applications in which our products are used could have a significant effect on the demand for our products. Research and development budgets fluctuate due to changes in available resources, mergers of pharmaceutical and biotechnology companies, spending priorities and institutional budgetary policies. Our business could be seriously damaged by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, academic institutions or government and private laboratories. In addition, short term changes in administrative, regulatory or purchasing-related procedures can create uncertainties or other impediments which can contribute to lower sales.

In recent years, the pharmaceutical and biotech industries have undergone substantial restructuring and consolidation. Additional mergers or corporate consolidations in the pharmaceutical industry could cause us to lose existing customers and potential future customers, which could have a material adverse effect on our business, financial condition and results of operations.

A significant portion of our sales have been to researchers, universities, government laboratories and private foundations whose funding is dependent upon grants from government agencies, such as the U.S. National Institutes of Health (NIH) and similar domestic and international agencies. Although the level of research funding has increased during the past several years, we cannot assure you that this trend will continue. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. The predictability of our revenues may be adversely affected if our customers delay purchases as a result of uncertainties surrounding the approval of government or industrial budget proposals. Also, government proposals to reduce or eliminate budgetary deficits have sometimes included reduced allocations to the NIH and other government agencies that fund research and development activities. A reduction in government funding for the NIH or other government research agencies could seriously and negatively impact our business.

### **We have encountered delays in receipt of some European reimbursement approvals and public health funding, which has impacted our ability to grow revenues in these markets.**

Third-party payors are often reluctant to reimburse healthcare providers for the use of medical tests such as our HPV test products, that involve new technology. In addition, third-party payors are increasingly limiting

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reimbursement coverage for medical diagnostic products and, in many instances, are exerting pressure on diagnostic product suppliers to reduce their prices. Because each third-party payor individually approves reimbursement, obtaining such approvals is a time-consuming and costly process that requires us to provide scientific and clinical support for the use of each of our products for which we seek reimbursement to each payor separately with no assurance that such approval will be obtained. This process can delay the broad market introduction of new products and could have a negative effect on our revenues and operating results. As a result, outside the U.S., third-party reimbursement may not be consistently available or financially adequate to cover the cost of our products. This could limit our ability to sell our products, cause us to reduce the prices of our products or otherwise adversely affect our operating results.

### **We heavily rely on air cargo carriers and other overnight logistics services.**

Our customers within the scientific research markets typically do not keep a significant inventory of QIAGEN products and consequently require overnight delivery of purchases. As such, we heavily rely on air cargo carriers such as DHL, FedEx and Panalpina. If overnight services are suspended or delayed and other delivery carriers cannot provide satisfactory services, customers may suspend a significant amount of work requiring nucleic acid purification. If there are no adequate delivery alternatives available, sales levels could be negatively affected.

### **We depend on suppliers for materials used to manufacture our products and if shipments from these suppliers are delayed or interrupted, we may be unable to manufacture our products.**

We buy materials for our products from many suppliers and are not dependent on any one supplier or group of suppliers for our business as a whole. However, key components of certain products, including certain instrumentation components and chemicals, are available only from a single source. If supplies from these vendors were delayed or interrupted for any reason, we may not be able to obtain these materials timely or in sufficient quantities or qualities in order to produce certain products, and our sales levels could be negatively affected.

### **We rely on collaborative commercial relationships to develop some of our products.**

Our long-term business strategy has included entering into strategic alliances and marketing and distribution arrangements with academic, corporate and other partners relating to the development, commercialization, marketing and distribution of certain of our existing and potential products. There can be no assurance that we will continue to be able to negotiate such collaborative arrangements on acceptable terms, or that any such relationships will be scientifically or commercially successful. In addition, there can be no assurance that we will be able to maintain such relationships or that our collaborative partners will not pursue or develop competing products or technologies, either on their own or in collaboration with others.

### **Doing business internationally creates certain risks for our business.**

Our business involves operations in several countries outside of the United States. Our consumable manufacturing facilities are located in Germany, China, and the United States, and our instrumentation facility is located in Switzerland. We also have established sales subsidiaries in numerous countries, including the United States, Germany, Japan, the United Kingdom, France, Switzerland, Australia, Canada, Austria, The Netherlands, Sweden, Italy, Hong Kong, Singapore, Turkey, Korea, Malaysia, China and Brazil. In addition, our products are sold through independent distributors serving more than 40 other countries. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. We have invested heavily in computerized information systems in order to manage more efficiently the widely dispersed components of our operations. We use SAP as our business information system to integrate most of our North American, European and Japanese subsidiaries.

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Our operations are also subject to other risks inherent in international business activities, such as general economic conditions in the countries in which we operate, overlap of different tax structures, unexpected changes in regulatory requirements, compliance with a variety of foreign laws and regulations, and longer accounts receivable payment cycles in certain countries. Other risks associated with international operations include import and export licensing requirements, trade restrictions, exchange controls and changes in tariff and freight rates. As a result of these conditions, an inability to successfully manage our international operations could have a material adverse impact on our operations.

**We have made investments in and are expanding our business into emerging markets and regions, which exposes us to new risks.**

Recently, we have expanded our business into emerging markets in Asia and South America, and we expect to continue to focus on growing our business in these regions. In addition to the currency and international operation risks described above, our international operations are subject to a variety of risks including risks, arising out of the economy, the political outlook and the language and cultural barriers in countries where we have operations or do business. In many of these emerging markets, we may be faced with several risks that are more significant than in the other countries in which we have a history of doing business. These risks include economies that may be dependent on only a few products and are therefore subject to significant fluctuations, weak legal systems which may affect our ability to enforce contractual rights, possible exchange controls, unstable governments, privatization actions or other government actions affecting the flow of goods and currency. In conducting our business, we move products from one country to another and may provide services in one country from a subsidiary located in another country. Accordingly, we are vulnerable to abrupt changes in customs and tax regimes that may have significant negative impacts on our financial condition and operating results.

**Our business in countries with a history of corruption and transactions with foreign governments increase the risks associated with our international activities.**

As we operate and sell internationally, we are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. and other business entities for the purpose of obtaining or retaining business. We have operations, agreements with third parties and make sales in countries known to experience corruption. Further international expansion may involve more exposure to such practices. Our activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents or distributors that could be in violation of various laws including the FCPA, even though these parties are not always subject to our control. It is our policy to implement safeguards to discourage these practices by our employees. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA may result in criminal or civil sanctions, which could be severe, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

**Our success depends on the continued employment of our key personnel, any of whom we may lose at any time.**

Our senior management consists of an Executive Committee comprised of our most senior executives responsible for core functions, the Chairman of which is Mr. Peer Schatz, our Chief Executive Officer. The loss of Mr. Schatz or any of our Managing Directors could have a material adverse effect on us. Further, although we have not experienced any difficulties attracting or retaining key management and scientific staff, our ability to recruit and retain qualified skilled personnel will also be critical to our success. Due to the intense competition for experienced scientists from numerous pharmaceutical and biotechnology companies and academic and other research institutions, there can be no assurance that we will be able to attract and retain such personnel on



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acceptable terms. Our planned activities will also require additional personnel, including management, with expertise in areas such as manufacturing and marketing, and the development of such expertise by existing management personnel. The inability to recruit such personnel or develop such expertise could have a material adverse impact on our operations.

### **Our business may require substantial additional capital, which we may not be able to obtain on terms acceptable to us, if at all.**

Our future capital requirements and level of expenses will depend upon numerous factors, including the costs associated with:

our marketing, sales and customer support efforts;

our research and development activities;

the expansion of our facilities;

the consummation of possible future acquisitions of technologies, products or businesses;

the demand for our products and services; and

the refinancing of debt.

We currently anticipate that our short-term capital requirements will be satisfied by the results of operations. However, we have outstanding loan facilities at December 31, 2007 of approximately \$500.0 million, of which \$25.0 million will become due in July 2009, \$50.0 million will become due in July 2010, \$75.0 million will become due in July 2011, and \$350.0 million will become due in July 2012. As of December 31, 2007, we also had additional long-term debt obligations of \$450 million, of which \$150 million becomes due in July 2011 and \$300 million becomes due in November 2012. Furthermore, as of December 31, 2007, we have capital lease obligations, including the current portion, of \$35.8 million, that expire in various years through 2018. To the extent that our existing resources are insufficient to fund our activities, we may need to raise funds through public or private debt or equity financings. No assurance can be given that such additional funds will be available or, if available, can be obtained on terms acceptable to us. If adequate funds are not available, we may have to reduce expenditures for research and development, production or marketing, which could have a material adverse effect on our business. To the extent that additional capital is raised through the sale of equity or convertible securities, the issuance of such securities could result in dilution to our shareholders.

### **An impairment of goodwill and intangible assets could reduce our earnings.**

At December 31, 2007, our consolidated balance sheet reflected approximately \$1.1 billion of goodwill and approximately \$639.1 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair market value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles generally require us to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If we determine that any of our goodwill or intangible assets were impaired, we would be required to take an immediate charge to earnings with a correlative effect on partners' equity and balance sheet leverage, as measured by debt to total capitalization.

### **Our strategic equity investments may result in losses.**

We have made and may continue to make strategic investments in complementary businesses as the opportunities arise. We periodically review the carrying value of these investments for impairment, considering factors, such as the most recent stock transactions, book values from the most recent financial statements, and forecasts and expectations of the investee. The results of these valuations may fluctuate due to market conditions and other conditions over which we have no control. Estimating the fair value of non-marketable equity



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investments in life science companies is inherently subjective. If actual events differ from our assumptions and other than temporary unfavorable fluctuations in the valuations of the investments are indicated, it could require a write-down of the investment. This could result in future charges on our earnings that could materially impact our results of operations. It is uncertain whether or not we will realize any long term benefits from these strategic investments.

### **Exchange rate fluctuations may adversely affect our business.**

Since we currently market our products in over 40 countries throughout the world, a significant portion of our business is conducted in currencies other than the U.S. dollar, our reporting currency. As a result, fluctuations in value, relative to the U.S. dollar, of the currencies in which we conduct our business have caused and will continue to cause foreign currency transaction gains and losses. Foreign currency transaction gains and losses arising from normal business operations are charged against earnings in the period when incurred. We hedge a portion of the anticipated cash flow that we expect to exchange into other currencies, subject to our short-term financing needs. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effects of exchange rate fluctuations upon future operating results. While we engage in foreign exchange hedging transactions to manage our foreign currency exposure, there can be no assurance that our hedging strategy will adequately protect our operating results from the effects of future exchange rate fluctuations.

### **We have a significant amount of long-term debt which may adversely affect our financial condition.**

We have a significant amount of debt which carries with it significant debt service obligations. A high level of indebtedness increases the risk that we may default on our debt obligations. We cannot assure you that we will be able to generate sufficient cash flow to pay the interest on our debt or that future working capital, borrowings or equity financing will be available to repay or refinance such debt. If we are unable to generate sufficient cash flow to pay the interest on our debt, we may have to delay or curtail our research and development programs. The level of our indebtedness, among other things, could:

make it difficult for us to make required payments on our debt;

make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

make us more vulnerable in the event of a downturn in our business.

### **The time and expense needed to obtain regulatory approval and respond to changes in regulatory requirements could adversely affect our ability to commercially distribute our products and generate revenue therefrom.**

We and our customers operate in a highly regulated environment characterized by continuous changes in the governing regulatory framework. Genetic research activities as well as products commonly referred to as genetically engineered, such as certain food and therapeutic products, are subject to governmental regulation in most developed countries, especially in the major markets for pharmaceutical and diagnostic products (*i.e.*, the European Union, the United States, and Japan). In the recent past, several highly publicized scientific successes (most notably in the areas of genomic research and cloning) have stirred a public debate in which ethical, philosophical and religious arguments have been raised against an unlimited expansion of genetic research and the use of products developed thereby. As a result of this debate, some key countries might increase the existing regulatory barriers; this, in turn, could adversely affect the demand for our products and prevent us from fulfilling our growth expectations. Furthermore, there can be no assurance that any future changes of applicable regulations will not require further expenditures or an alteration, suspension or liquidation of our operations in certain areas, or even in their entirety.

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Changes in the existing regulations or adoption of new requirements or policies could adversely affect our ability to sell our approved products or to seek to introduce new products in other countries around the world. Sales volumes of certain of our products in development may be dependent on commercial sales by us or by our customers of diagnostic and pharmaceutical products, which will require pre-clinical studies, clinical trials and other regulatory clearance. Such trials will be subject to extensive regulation by governmental authorities in the United States, including the FDA, international agencies and agencies in other countries with comparable responsibilities. These trials involve substantial uncertainties and could impact customer demand for our products. In addition, certain of our products, especially products intended for use in in vitro diagnostics applications, are dependent on regulatory or other clearance. For example, since the European Union Directive 98/79/EC on in vitro diagnostic medical devices, or EU-IvD-D, went into effect on December 7, 2003, all products and kits which are used for in vitro diagnostic applications must be compliant with this directive. In addition to high risk products such as HIV testing systems (list A of Annex II of the directive) or blood glucose testing systems (list B of Annex II of the directive), nucleic acid purification products which are used in diagnostic workflows are affected by this regulatory framework. The major goals of this directive are to standardize the diagnostic procedures within the European Union, to increase reliability of diagnostic analysis and to enhance patients' safety through the highest level of product safety. These goals are expected to be achieved by the enactment of a large number of mandatory regulations for product development, production, quality control and life cycle surveillance. Our failing to obtain any required clearance or approvals may significantly damage our business in such segments.

Additionally, we may be required to incur significant costs to comply with laws and regulations in the future, and changes or additions to existing laws or regulations may have a material adverse effect upon our business, financial condition and results of operations.

The key products and product candidates we acquired in our acquisition of Digene are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug and Cosmetic Act. Governmental bodies in other countries also have medical device approval regulations which are becoming more extensive. Such regulations govern the majority of the commercial activities previously performed by Digene (which are now performed by us), including the indications for which these products can be used, product development, product testing, product labeling, product storage, use of these products with other products and the manufacturing, advertising and promotion of these products for the approved indications. Compliance with these regulations is expensive and time-consuming. With respect to our HPV test products, Digene was the first company to obtain approval of regulatory applications for HPV testing in the United States and in many countries in Europe, which adds to our expense and increases the degree of regulatory review and oversight. The expense of submitting regulatory approval applications in multiple countries as compared to our available resources will impact the decisions we make about entering new markets.

Each medical device that we wish to distribute commercially in the United States will likely require either 510(k) clearance or pre-market approval from the FDA prior to marketing the device for in vitro-diagnostic use. Clinical trials related to our regulatory submissions take years to execute and are a significant expense. The 510(k) clearance pathway usually takes from three to twelve months, but can take longer. The pre-market approval pathway is much more costly, lengthy and uncertain and can take from one to three years, or even longer. It took more than four years to receive pre-market approval to offer our current generation HPV test product to test for the presence of HPV in women with equivocal Pap test results and pre-market approval to use our HPV Test as a primary adjunctive cervical cancer screening test to be performed in conjunction with the Pap test for women age 30 and older. The regulatory time span increases our costs to develop new products and increases the risk that we will not succeed in introducing or selling new products in the United States.

Our cleared or approved devices, including our diagnostic tests and related equipment, are subject to numerous post-market requirements. We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA determines that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions.

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such as fines, injunctions and civil penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of production, denial of our requests for 510(k) clearance or pre-market approval of product candidates, withdrawal of 510(k) clearance or pre-market approval already granted and criminal prosecution. Any enforcement action by the FDA may also affect our ability to commercially distribute these products in the United States.

### **Risk of price controls is a threat to our profitability.**

The ability of many of our customers to successfully market their products depends in part on the extent to which reimbursement for the costs of these products is available from governmental health administrations, private health insurers and other organizations. Governmental and other third party payors are increasingly seeking to contain healthcare costs and to reduce the price of medical products and services. Therefore, the biotechnology, diagnostics and pharmaceutical industries are exposed to the potential risk of price controls by these entities. If there are not adequate reimbursement levels, the commercial success of our customers and, hence, our self, could be adversely affected.

### **Our business exposes us to potential liability.**

The marketing and sale of our products and services for certain applications entail a potential risk of product liability, and, although we are not currently subject to any material product liability claims, there can be no assurance that product liability claims will not be brought against us. Further, there can be no assurance that our products will not be included in unethical, illegal or inappropriate research or applications, which may in turn put us at risk of litigation. We currently carry product liability insurance coverage, which is limited in scope and amount, but which we believe is currently appropriate for our purposes. There can be no assurance, however, that we will be able to maintain such insurance at reasonable cost and on reasonable terms, or that such insurance will be adequate to protect us against any or all potential claims or losses.

We are subject to various laws and regulations generally applicable to businesses in the different jurisdictions in which we operate, including laws and regulations applicable to the handling and disposal of hazardous substances. We do not expect compliance with such laws to have a material effect on our capital expenditures, earnings or competitive position. Although we believe that our procedures for handling and disposing of hazardous materials comply with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could have a material adverse effect on us.

### **Our holding company structure makes us dependent on the operations of our subsidiaries.**

We were incorporated under Dutch law as a public limited liability company (naamloze vennootschap) and we are organized as a holding company. Currently, our material assets are the outstanding shares of our subsidiaries. We, therefore, are dependent upon payments, dividends and distributions from our subsidiaries for funds to pay our operating and other expenses and to pay future cash dividends or distributions, if any, to holders of our Common Shares. Dividends or distributions by subsidiaries to us in a currency other than the U.S. dollar may result in a loss upon a subsequent conversion or disposition of such foreign currency, including a subsequent conversion into U.S. dollars.

### **Our debt service obligations may adversely affect our cash flow.**

We have a significant amount of debt which carries with it significant debt service obligations. A high level of indebtedness increases the risk that we may default on our debt obligations. We cannot assure you that we will be able to generate sufficient cash flow to pay the interest on our debt or that future working capital, borrowings

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or equity financing will be available to repay or refinance such debt. If we are unable to generate sufficient cash flow to pay the interest on our debt, we may have to delay or curtail our research and development programs. The level of our indebtedness among other things could:

make it difficult for us to make required payments on our debt;

make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

make us more vulnerable in the event of a downturn in our business

**Our Common Shares may have a volatile public trading price.**

The market price of the Common Shares since our initial public offering in September 1996 has increased significantly and been highly volatile. In the last two fiscal years, the closing price of our Common Shares has ranged from a high of \$23.55 to a low of \$11.72 on the NASDAQ, and a high of EUR 16.24 to a low of EUR 9.55 on the Frankfurt Stock Exchange. In addition to overall stock market fluctuations, factors which may have a significant impact on the market price of the Common Shares include:

announcements of technological innovations or the introduction of new products by us or our competitors;

developments in our relationships with collaborative partners;

quarterly variations in our operating results or those of companies related to us;

changes in government regulations or patent laws;

developments in patent or other proprietary rights;

developments in government spending for life sciences related research; and

general market conditions relating to the diagnostics, applied testing, pharmaceutical and biotechnology industries.

The stock market has from time to time experienced extreme price and trading volume fluctuations that have particularly affected the market for technology-based companies and that have not necessarily been related to the operating performance of such companies. These broad market fluctuations may adversely affect the market price of our Common Shares.

**Holders of our Common Shares will not receive dividend income.**

We have not paid cash dividends since our inception and do not anticipate paying any cash dividends on our Common Shares for the foreseeable future. Although we do not anticipate paying any cash dividends, any cash dividends paid in a currency other than the U.S. dollar will be subject

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to the risk of foreign currency transaction losses. Investors should not invest in our Common Shares if they are seeking dividend income; the only return that may be realized through investing in our Common Shares is through the appreciation in value of such shares.

### **Future sales of our Common Shares could adversely affect our stock price.**

Future sales of substantial amounts of our Common Shares in the public market, or the perception that such sales may occur, could adversely affect the market price of the Common Shares. Under Dutch law, a company can issue shares up to its authorized share capital provided for in its articles of association. Pursuant to our Articles of Association as amended on October 11, 2007, our authorized share capital amounts to EUR

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9.0 million, divided into 410.0 million Common Shares, 40.0 million financing preference shares and 450.0 million preference shares, with all shares having a EUR 0.01 par value. As of December 31, 2007, we had outstanding 195.3 million Common Shares plus 12.9 million additional shares subject to outstanding stock options and awards, of which 11.2 million were vested. A total of approximately 19.9 million Common Shares are reserved and available for issuances under our stock plans, including those shares subject to outstanding stock options and awards. The resale of Common Shares issued in connection with the exercise of certain stock options are subject to some restrictions. All of our outstanding Common Shares are freely saleable except shares held by our affiliates, which are subject to certain limitations on resale. Additionally, holders of notes issued by QIAGEN Finance (Luxembourg) S.A. and QIAGEN Euro Finance (Luxembourg) S.A. are entitled to convert their notes into approximately 26.9 million Common Shares, subject to adjustments in certain cases.

**Provisions of our Articles of Association and Dutch law and an option we have granted may make it difficult to replace or remove management and may inhibit or delay a takeover.**

Our Articles of Association, or Articles, provide that our shareholders may only suspend or dismiss our managing and supervisory directors against their wishes with a vote of two-thirds of the votes cast if such votes represent more than 50% of the outstanding Common Shares unless the proposal was made by the joint meeting of the Supervisory Board and the Managing Board in which case a simple majority is sufficient. They also provide that if the members of our Supervisory Board and our Managing Board have been nominated by the joint meeting of the Supervisory Board and Managing Board, shareholders may only overrule this nomination with a vote of two-thirds of the votes cast if such votes represent more than 50% of the outstanding Common Shares. Certain other provisions of our Articles allow us, under certain circumstances, to prevent a third party from obtaining a majority of the voting control of our Common Shares by issuing preference shares. Pursuant to our Articles and the resolution adopted by our General Meeting on June 16, 2004, QIAGEN's Supervisory Board is entitled to resolve to issue Preference Shares in case of an intended take-over of our Company by (i) any person who alone or with one or more other persons, directly or indirectly, have acquired or given notice of an intent to acquire (beneficial) ownership of an equity stake which in aggregate equals 20% or more of our share capital then outstanding or (ii) an adverse person as determined by the Supervisory Board. If the Supervisory Board opposes an intended take-over and authorizes the issuance of preference shares, the bidder may withdraw its bid or enter into negotiations with the Managing Board and/or Supervisory Board and agree on a higher bid price for our shares.

In 2004, we granted an option to the Stichting Preferente Aandelen QIAGEN (the Foundation (*Stichting*)), subject to the conditions described in the paragraph above, which allows the Foundation to acquire preference shares from us. The option enables the Foundation to acquire such number of preference shares as equals the number of our outstanding Common Shares at the time of the relevant exercise of the right less one share. When exercising the option and exercising its voting rights on such shares, the Foundation must act in our interest and the interests of our stakeholders. The purpose of the Foundation option is to prevent or delay a change of control that would not be in the best interests of us and our stakeholders. An important restriction on the Foundation's ability to prevent or delay a change of control is that issuing (preference or other) protective shares enabling the Foundation to exercise 30% or more of the voting rights without the obligation to make a mandatory offer for all shares held by the remaining shareholders, is only allowed after a public offer has been announced by a third party. In addition, the holding of such a block of shares by the Foundation is restricted to two years and as a consequence, the size of the protective stake will need to be decreased below the 30% voting rights threshold before the two year period lapses.

**United States civil liabilities may not be enforceable against us.**

We are incorporated under the laws of The Netherlands and substantial portions of our assets are located outside of the United States. In addition, certain members of our Managing and Supervisory Boards and our officers and certain experts named herein reside outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or such other persons, or to enforce outside



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the U.S. judgments obtained against such persons in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. securities laws. In addition, it may be difficult for investors to enforce, in original actions brought in courts in jurisdictions located outside the United States, rights predicated upon the U.S. securities laws. There is no treaty between the United States and The Netherlands for the mutual recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the federal securities laws, would not be directly enforceable in The Netherlands. However, if the party in whose favor such final judgment is rendered brings a new suit in a competent court in The Netherlands, such party may submit to the Dutch court the final judgment which has been rendered in the United States. If the Dutch court finds that the jurisdiction of the federal or state court in the United States has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the Dutch court will, in principle, give binding effect to the final judgment which has been rendered in the United States unless such judgment contravenes Dutch principles of public policy. Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us, members of our Managing or Supervisory Boards, officers or certain experts named herein who are residents of The Netherlands or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the federal securities laws. In addition, there is doubt as to whether a Dutch court would impose civil liability on us, the members of our Managing or Supervisory Boards, our officers or certain experts named herein in an original action predicated solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in The Netherlands against us or such members, officers or experts, respectively.

### **Item 4. Information on the Company**

#### *History and Development of the Company*

QIAGEN N.V. is registered under its commercial and legal name QIAGEN N.V. with the trade register (*kamer van koophandel*) of the Dutch region Limburg Noord under file number 12036979. We began operations as a German company in 1986. On April 29, 1996, we were incorporated as QIAGEN N.V., a public limited liability company (*naamloze vennootschap*) under Dutch law as a holding company. Our legal seat is in Venlo, The Netherlands. Our principal executive office is located at Spoorstraat 50, 5911 KJ Venlo, The Netherlands, and our telephone number is +31-77-320-8400. As a holding company, we conduct our business through our subsidiaries located throughout the world, including subsidiaries in Europe, Japan, Australia, North America and East Asia. Further information about QIAGEN can be found at [www.qiagen.com](http://www.qiagen.com).

Since 1986, we have developed and marketed a broad range of proprietary products for the academic and industrial research markets as well as for the applied testing and molecular diagnostics markets. Our objective is to expand our leadership position in all markets we serve. We have experienced significant growth in the past, with a five year compound annual growth through December 31, 2007 of approximately 17% in net sales and net income, as reported under U.S. GAAP. We have funded our growth through internally generated funds, debt, and private and public sales of equity securities. In recent years, we have made a number of strategic acquisitions and disposals expanding and focusing our technology and product offerings. Significant events in the development of our business in 2007 include:

In April 2007, our subsidiary QIAGEN North American Holdings, Inc. signed a definitive merger agreement with eGene, Inc. (OTCBB: EGEI) pursuant to which eGene became a wholly-owned subsidiary of QIAGEN North American Holdings, Inc. eGene is an early-stage company located in Irvine, California that has developed and is commercializing a patented sample separation and analysis technology based on capillary electrophoresis. The acquisition was completed in July 2007 for approximately \$30.3 million including cash and equity.

In July 2007, we completed the acquisition of Digene Corporation (NASDAQ: DIGE) through a tender offer and subsequent merger of Digene with and into a wholly-owned subsidiary of QIAGEN N.V. Following the completion of the merger, Digene became a wholly owned subsidiary of QIAGEN North

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American Holdings, Inc. and was subsequently renamed QIAGEN Gaithersburg, Inc. In the aggregate, net of cash acquired, the consideration totaled approximately \$1.5 billion including cash and equity. The merger combines our leading portfolio of sample and assay technologies, including a broad panel of molecular diagnostic tests, with Digene's leadership in HPV-targeted molecular diagnostic testing, creating a global leader in molecular diagnostics outside blood screening and viral load monitoring.

In December 2007, we entered into a joint venture with BioOne\* Capital to establish Dx Assay Pte Ltd, one of the first centers in Singapore for assay development in which molecular diagnostics for infectious and genetic diseases will be developed.

In 2008, we were awarded an exclusive contract by the Singapore Ministry of Health to supply sample preparation solutions and molecular tests for the specific detection of Influenza H5N1 viruses (avian flu virus). The contract with the Singapore Ministry of Health is the latest supply agreement of QIAGEN with public and private institutions engaged in H5N1 surveillance. More than 80 institutes worldwide involved in the surveillance of avian flu infection use procedures and reagents developed and offered by QIAGEN.

Also in 2008, we introduced the QIASymphony SP, the first system of a novel modular processing platform, which can be integrated to automate entire workflows from sample to result. The QIASymphony offers the highest flexibility, convenience and safety for a broad range of sample and assay applications.

### **Business Overview**

#### ***Description of Our Business***

We believe, based on the nature of our products and technologies and on our United States and European market shares as supported by independent market studies, that we are the world's leading provider of innovative sample and assay technologies and products. Sample technologies are used to collect, stabilize, isolate and purify deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins from any biological sample. Assay technologies are then used to make specific target biomolecules, such as the DNA of a specific virus, visible for subsequent detection and analysis. Our products are considered standards in areas such as pre-analytical sample preparation and assay solutions in research for life sciences, applied testing and molecular diagnostics.

Our sample technologies provide access to the content of biological samples. These include solutions for the collection, stabilization, purification, handling and storage of any analyte (DNA, RNA, protein) from any sample (blood, bone, tissue, etc.). They ensure that a sample is processed in a reproducible, standardized method with the highest level of quality before entering the subsequent analysis phase, for which the Company provides a broad range of reagents and testing solutions.

Our assay technologies include reagents which enable the detection of such purified target analytes. We also provide closed assays, which have been pre-configured to test for specific targets such as the influenza virus, hepatitis, HIV or herpes. QIAGEN holds a unique leadership position in HPV-testing, one of the largest and most rapidly expanding market segments in both women's health testing and molecular diagnostics. The Company provides the only FDA approved and CE marked test which screens for the presence of high-risk HPV viruses that cause cervical cancer. QIAGEN plans to market the test worldwide through its dedicated sales force and to offer accompanying tests for Gonorrhea, Chlamydia, and other pathogens, which are expected to form the core of our new women's health products portfolio.

#### ***Our Products***

We have developed more than 500 consumable products and automated solutions. We sell these products to academic research markets, to leading pharmaceutical and biotechnology companies, to molecular diagnostics laboratories as well as to customers in applied testing markets, such as forensics, animal or food testing, and

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pharmaceutical process control. These products enable our customers to efficiently pursue their research and commercial goals that require the use of nucleic acids.

The main categories of our products include:

### *Consumables:*

Our consumable products include our sample and assay technologies. Sample technologies are used to collect, stabilize, isolate and purify DNA, RNA and proteins from all biological samples such as blood or tissue. Assay technologies like our molecular diagnostic assays are used to make such isolated biomolecules visible. We offer most of our sample and assay consumable products, which account for about 90% of our business, in kit form to maximize customer convenience and reduce user error. These kits contain all necessary reagents and buffers, and a technical handbook that includes a detailed protocol and background information. Each kit is sufficient to support a number of applications varying from one to one thousand depending on the kit. Each kit is covered by our quality guarantee.

Major applications for our consumable products are plasmid DNA purification; DNA testing for HPV, RNA stabilization and purification; genomic and viral nucleic acid purification; nucleic acid transfection; polymerase chain reaction (PCR) amplification; reverse transcription; DNA cleanup after PCR and sequencing; DNA cloning and protein purification. In 2005, we began offering validated PCR assays which allow PCR-based detection of viral, bacterial and parasite, human and animal pathogens as well as pharmacogenomic genotyping. In 2007, we acquired Digene Corporation and began offering the HC2 HPV Test, a signal amplified test for the Human Papillomavirus for use in cervical cancer screening programs. The majority of assays are validated with either manual QIAamp sample preparation or automated MagAttract sample preparation from QIAGEN and CE-labeled according to the IvD-Directive in EU.

### *Instrumentation:*

Our automated systems perform automated nucleic acid preparation of the above mentioned consumables in low, medium or high throughput scale as well as reaction set-up, allowing customers to perform reliable low- to high-throughput nucleic acid sample preparation, assay setup and other laboratory tasks.

Our automated systems offer walk-away automation of sample and assay technologies in low, medium or high throughput scale, as well as reaction set-up and other laboratory tasks. We also sell instruments to our OEM partners. In early 2007, we launched the QIAcube, a novel sample processing platform incorporating novel and proprietary technologies which allow users in research in life sciences, applied testing and molecular diagnostics to fully automate the processing of almost all our consumable products. The QIAcube received the distinguished New Product Award, or NPA, Designation of the Association for Laboratory Automation, or ALA, in February, 2007 and the QIASymphony, which was introduced in January 2008, received the ALA NPA in 2008.

### *Other:*

A very small part of our business revenues comes from custom services, such as whole genome amplification services, DNA sequencing, and non-cGMP DNA production on a contract basis. We also sell and/or license technology.

In 2007, we launched 72 new products, including sample and assay technologies for research in the areas of epigenetics, gene expression, micro RNA, proteomics, RNAi, applied testing and molecular diagnostics as well as platform solutions such as the very successful QIAcube.

## ***Research and Development***

By focusing our resources on our core expertise **Sample & Assay Technologies**, we can invest more in research and development than we believe is typical in our industry. Over 460 employees in research and development, who work in five centers of excellence on three different continents, constantly develop new

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applications that push the frontiers of science further. Rapid, proven innovation cycles promise fast introductions of new technologies which meet the needs of today's labs. Our investment in research and development accounts for more than 10% of our sales. Our total research and development expenses in 2007, 2006 and 2005 were approximately \$64.9 million, \$41.6 million, and \$35.8 million, respectively. We have fast, proven innovation cycles, with four percent of 2007 revenue growth stemming from new products launched in 2007. Our comprehensive intellectual property portfolio spans over 630 granted patents and more than 600 pending applications.

Our product development efforts are focused on expanding our existing products and developing innovative new products in selected areas where we have expertise and have identified substantial unmet market needs. We intend to maintain our technology leadership position through investments in product improvements, product extensions, and innovative new approaches. We believe that improvements in instrumentation will strengthen our leadership position in the automation of pre-analytical processing applications and generate an increased demand for our consumable products.

### ***Sales and Marketing***

We market our products in more than 40 countries throughout the world. We have established subsidiaries in the markets that we believe have the greatest sales potential including but not limited to the United States, Germany, the United Kingdom, Switzerland, France, Japan, Australia, Canada, Italy, and throughout Asia. We have established a network of highly experienced marketing personnel and employ a dedicated field sales force of over 900 people, who sell our products and provide direct support to customers. A significant number of our marketing and sales staff are experienced scientists with academic degrees in molecular biology or related areas. We also have specialized independent distributors and importers.

Our marketing strategy is focused on providing high-quality products that offer customers unique advantages, coupled with a commitment to technical excellence and customer service. We have developed a range of marketing tools designed to provide customers with direct access to technical support and to inform them of new product offerings, as well as to enhance our reputation for technical excellence, high-quality products, and commitment to customer service. One such tool is our technical service hotline, which allows existing or potential customers to discuss, via phone and e-mail, a wide range of technical questions regarding our products and related molecular biology procedures with Ph.D. and M.Sc. scientists in our technical service group, who provide this advice and training. Frequent communication with customers enables us to identify market needs, to gain early insight into new developments and business opportunities, and to respond with new products.

To enhance the knowledge base of clinicians and to provide for physician-directed marketing of our products, we have sales representatives dedicated to educating physicians, nurses and other healthcare professionals about the benefits of HPV testing using hybrid capture 2, or HC2, technology. Additionally, we have implemented direct-to-consumer (DTC) advertising campaigns designed to educate women about the link between HPV and cervical cancer and the availability of our HC2 HPV Test. We plan to continue the DTC campaign during 2008.

We also distribute several publications, including our annual catalog, to existing and potential customers worldwide, providing new product information, product updates, and articles contributed by customers and by our scientists about existing and new applications for our products. In addition, we advertise in leading scientific journals such as *Science*, and hold numerous scientific seminars, in which our scientists present technical information at leading academic and industrial research institutes worldwide. We conduct direct mail campaigns to announce new products or offer special sales promotions, and also offer various personalized electronic newsletters for our worldwide customers that provide helpful hints and information for molecular biology applications. Our web site ([www.qiagen.com](http://www.qiagen.com)) contains a full on-line product catalog and online ordering system, various support tools and resources. Some information is available on our website in French and German to support these local markets. We also have a Japanese language site ([www.qiagen.co.jp](http://www.qiagen.co.jp)). The information contained in, or that can be accessed through, our website is not part of this Annual Report.

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In addition to keeping our customers informed of new product offerings, we also offer an inventory consignment program. The QIAcabinet is a storage cabinet owned by us and placed in customer laboratories at their request. The QIAcabinet is stocked with our products, offering customers the convenience of immediate access, thereby reducing product reorder procedures and shipping costs. We monitor cabinet inventory and bill the customers at regular intervals as the products are used. We believe that our QIAcabinet helps us maintain our competitive position while also reducing distribution costs and increasing our visibility in the laboratory.

### ***Principal Markets***

From our inception, we have believed that nucleic acids and proteins would play an increasingly important role in molecular biology and that major new commercial uses of nucleic acids would be developed. We have been supplying customers with proprietary products for the processing of nucleic acids since 1986. Customers include major academic institutions and governmental laboratories, such as the United States National Institutes of Health, or NIH, as well as leading pharmaceutical and biotechnology companies. In addition, fundamental developments in recent years have created significant new opportunities for us in the emerging markets of nucleic acid-based molecular diagnostics, such as HPV-testing, and applied testing, such as forensics, veterinary diagnostics, testing of genetically modified organism, or GMO, and other food testing, drug discovery and development. In response to these opportunities, we are currently targeting our products and marketing activities to each of these markets.

### ***Research Market***

The worldwide research market for nucleic acid and protein separation and purification products is comprised of an estimated 45,000 academic and industrial research laboratories with more than 400,000 researchers from leading academic institutions, diagnostics companies and laboratories, biotechnology companies and pharmaceutical companies. A substantial portion of this market continues to utilize traditional, labor intensive methods for nucleic acid separation and purification, and we estimate that 15 percent of all molecular biology research time is spent on such processes. We recognized the opportunity to replace the traditional methods with reliable, fast, and high-quality nucleic acid separation and purification technologies and products. We concentrated our product development and marketing efforts on this market and now offer over 500 nucleic acid sample processing products to customers. We also offer a broad and innovative portfolio for the expression, purification and fractionation of proteins. We believe that we are the technology leader in this growing research market and that we are well positioned to increase sales and expand our share of the research market as laboratories continue to convert from traditional methods to newer technologies such as ours. Based on estimates of the number of sample preparations being performed each year, we believe that the potential worldwide research market for our nucleic acid purification products exceeds \$1 billion, as the majority of the market currently uses home-brew methodology. In addition, we believe that an additional \$800 million is spent annually in this market on PCR enzymes and reagents. We have expanded our product base for PCR amplification and reverse transcription and continue to develop products for the PCR-related market segment. In 2005 we were one of the first companies to enter into a broad licensing agreement with Applied Biosystems Group regarding real-time PCR technology. This agreement enhances our value as a leading supplier of a broad range of real-time PCR technologies. These real-time PCR technologies are optimized for use with our market- and technology-leading preanalytical solutions. Our PCR reagent portfolio is also a critical component for ready-to-use real-time PCR assays which we offer and which are linked to our innovative RNAi assay offering.

### ***Molecular Diagnostics Market***

We believe that the molecular diagnostics market represents a significant market for nucleic acid sample technology products. We believe that the advent of PCR and other amplification technologies has made the prospect of nucleic acid-based molecular diagnostics feasible. Molecular diagnostics have fundamental advantages over traditional diagnostic technologies, such as immunoassays, in potential applications and clinical specificity and sensitivity.

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This new generation of molecular diagnostics can be used, for example, to detect or identify micro-organisms, cancer cells, bacteria and viruses (including HIV) by searching for their nucleic acid sequences. In order to prove that a disease is present in a patient, the unique sequence of the target nucleic acid causing the disease must be known, and the sequence in the sample must be amplified to facilitate detection. Potential commercial applications for nucleic acid-based molecular diagnostics include infectious disease diagnostics in bio banks, HLA typing for bone marrow and organ transplantation, genetic testing for predisposition to cancers and other common diseases, and genetic fingerprinting of humans, animals and plants.

We believe clinical sensitivity and specificity can be greatly enhanced by using nucleic acid-based information. In many cases, conventional diagnostic tests also lack the clinical sensitivity and specificity to provide definitive diagnoses during the early stages of disease. Clinical sensitivity is typically regarded as the measure of a test's ability to accurately detect the presence of disease. A false negative test result can lead to providing a negative or normal diagnosis to a patient who has the disease. Clinical specificity is typically regarded as the measure of a test's ability to correctly identify the absence of disease when it is not present. A false positive test result can lead to providing a positive or abnormal diagnosis to a patient who does not have disease.

For detection of HPV, we sell our products in the United States primarily for the two FDA-approved indications: adjunctive primary screening with a Pap test for women age 30 and older, and follow-up testing of equivocal Pap test results in women of any age. In Europe and the rest of the world, HPV testing is in varying stages of research and adoption, with most use limited to follow-up for equivocal Pap tests. We are aware of an increasing number of clinical trials being conducted to explore the use of HPV testing for primary screening, both with a Pap test or as a stand-alone initial test, as well as for proof of clearance or cure after treatment for diagnosed cervical disease or cancer.

The success of molecular diagnostics will depend on the ability to analyze purified nucleic acid samples from a variety of specimens, including blood, tissue, body fluids and stool, and on automation so that hundreds of samples can be handled concurrently. Other key factors will be the convenience, versatility, and reliability of the nucleic acid separation and purification procedures. Our automated systems series has been developed to handle low-, medium-, and high-throughput nucleic acid sample preparation and handling tasks in molecular biology laboratories, clinical laboratories, blood banks, forensic projects, and genomics projects. Nucleic acid samples purified on our instruments are ready for use in the demanding and sensitive downstream assays performed in molecular diagnostic applications. We offer closed and open assay technologies. The open platforms, such as real-time PCR or endpoint PCR, contain PCR reagents. Closed platforms, diagnostics with predefined targets, include Multiplexing and other pathogen detection assays. In order to broadly address the molecular diagnostics market, in May 2005 we acquired artus Gesellschaft für molekularbiologische Diagnostik und Entwicklung mbH, subsequently renamed QIAGEN Hamburg GmbH, which offers a broad range of real-time PCR assays for viral and bacterial pathogen detection that are complementary to our sample preparation kits. The majority of these assays are validated with either manual QIAamp sample preparation or automated MagAttract sample preparation and CE-labeled according to the EU-IVD-D. Assays are marketed directly to end customers by our sales channels and selected assays are marketed by major diagnostic partners with access to customers complementary to our customers. In addition, we intend to enter into partnerships or other agreements with established companies in the molecular diagnostics market in order to broaden the distribution of our products.

We expect molecular diagnostic tests to create a fundamental shift in both the practice of medicine and the economics of the diagnostics industry. Molecular based diagnostic tests are expected to create an increased emphasis on preventative and predictive molecular medicine. Physicians will be able to use these tests for the early detection of disease and to treat patients on a personalized basis, allowing them to select the most effective therapy with the fewest side effects. In addition, the relatively straight-forward format and significant automation capabilities of our tests allow ease of laboratory use, reducing overall processing costs.

**Table of Contents****Applied Testing Market**

We believe that emerging applied testing markets such as forensics, veterinary and food, offer great opportunities for standardized sample preparation and assay solutions. Successes in crime cases due to DNA analyses, public debates about GMO and food safety as well as bioterrorism risks, have increased the value of the use of molecular based methods. These methods are performed by well trained researchers in fully equipped laboratories as well as by less trained personnel calling for easy-to-use, reproducible and standardized methods. Our manual DNA and RNA purification methods and the automated solutions on BioRobot EZ1, BioSprint 15 and 96, as well as our amplification enzymes and quantitative assays address the needs in these markets. We market a range of assays to end users in applied testing markets, such as veterinary diagnostics and biodefense laboratories.

**Seasonality**

Our business does not experience predictable seasonality. Historically, a significant portion of our sales have been to researchers, universities, government laboratories and private foundations whose funding is dependent upon grants from government agencies, such as the U.S. NIH and similar domestic and international agencies. To the extent that our academic customers experience increases, decreases or delays in funding arrangements, and to the extent that any of our customers' activities are slowed, such as during vacation periods or due to delays in the approval of governmental budgets, including the U.S. federal government's budget, we may experience fluctuations in sales volumes during the year or delays from one period to the next in the recognition of sales.

**Revenue by Geographic Region**

The table below sets forth total revenue during each of the past three fiscal years by geographical market, which includes revenue from all of our product and service offerings. It is not practicable to provide a detail of revenues by category of activity. Net sales are attributed to countries based on the location of the subsidiary making the sale as certain subsidiaries have international distribution. See Note 19 to our consolidated financial statements included in Item 18. Financial Statements for additional information with respect to operations by geographic region.

Net Sales	2007	2006	2005
North America*	\$ 465,878,000	\$ 318,865,000	\$ 285,242,000
Germany*	270,173,000	220,325,000	187,381,000
Switzerland*	56,615,000	40,044,000	36,957,000
Asia*	71,168,000	49,875,000	35,266,000
Rest of World*	148,082,000	109,025,000	88,924,000
Corporate*	350,000	525,000	985,000
Subtotal	1,012,266,000	738,659,000	634,755,000
Intersegment Elimination+	(362,492,000)	(272,881,000)	(236,360,000)
Total	\$ 649,774,000	\$ 465,778,000	\$ 398,395,000

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\* Includes net sales to affiliates.

+ Represents intercompany sales between affiliates, which are accounted for by a formula based on local list prices and eliminated in consolidation.

**Intellectual Property, Proprietary Rights and Licenses**

We have made and may continue to make investments in intellectual property. In the years ended December 31, 2007, 2006 and 2005, our purchases of intangible assets have totaled approximately \$24.1 million, \$6.4 million, and \$15.3 million, respectively. We do not depend solely on any individual patent or technologies owned or licensed by us. We are however significantly dependent in the aggregate on technology that we own or license.

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Therefore, we consider the protection of our proprietary technologies and products as the key to the success of our business. We rely on a combination of patents, licenses and trademarks to establish and protect our proprietary rights in our technologies and products. We currently own 109 issued patents in the United States, 70 issued patents in Germany and 434 issued patents in other major industrialized countries, and have 619 pending patent applications. Worldwide, we own 613 granted patents. Our policy is to file patent applications in Western Europe, the United States and Japan. U.S. patents have a term of 17 years from the date of issue for patents issued from applications submitted prior to June 8, 1995, and 20 years from the date of filing of the application in the case of patents issued from applications submitted on or after June 8, 1995. Patents in most other countries have a term of 20 years from the date of filing the patent application. We intend to aggressively prosecute and enforce our patents and otherwise protect our proprietary technologies. We also rely on trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

Our practice is to require employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties, subject to a right to publish certain information in scientific literature in certain circumstances and to other specific exceptions. In the case of our employees, the agreements provide that all inventions conceived by the individual in the course of their employment will be our exclusive property.

See **Risk Factors** included in Item 3 above for details regarding risks related to our reliance on patents and proprietary rights.

### ***Partnerships, Alliances and Acquisitions***

Our strategy includes the use of strategic alliances to augment our product development efforts with complementary technologies and to leverage our marketing and distribution capabilities with respect to select market opportunities. In order to expand our business, we also intend to continue to pursue strategic investments in our acquisitions of complementary businesses and technologies as the opportunities arise. We currently develop integrated solutions for and together with many manufacturers from pharma and diagnostics, including Roche Diagnostics, Abbott Laboratories and Siemens.

### ***Competition***

We believe that our primary competition in sample technology products involves traditional separation and purification methods, such as phenol extraction, cesium chloride density gradient centrifugation, and precipitation. These methods utilize widely available reagents and other chemicals supplied by companies, such as Sigma-Aldrich Corp. and Roche Diagnostics GmbH (Applied Sciences Division). We compete with such methods through our innovative technologies and products, which offer a comprehensive solution for nucleic acid collection, pre-treatment, separation and purification needs and provide significant advantages over traditional methods with respect to speed, reliability, convenience, and ease of use.

We also experience, and expect to continue to experience, competition in different segments of our business from other companies providing sample preparation products in kit form and assay solutions. These competitors include: Promega Corp., Invitrogen Corp., Millipore Corp., Roche Diagnostics, and Macherey-Nagel GmbH for nucleic acid separation and purification; Applied Biosystems, Invitrogen Corp. and Promega Corp for assay solutions; Invitrogen Corp. and Promega Corp. for transfection reagents; and Sigma-Aldrich Corp. and Fisher Scientific for protein fractionation products. We believe that our proprietary technologies and products offer significant advantages over competitors products with regard to purity, speed, reliability and ease-of-use.

We also face competition from well established diagnostic technologies, such as cytology and, particularly in Europe, from emerging alternative HPV testing approaches, such as research-based PCR, other indicators of disease and other "home brew" testing methods developed by laboratories. With the increasing acceptance of the



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importance of HPV testing, we expect such competition will intensify. Our competitors include molecular diagnostic companies, such as Roche Diagnostics, Third Wave Technologies, Inc. and Gen-Probe, Inc., which are developing or marketing HPV products that have not been approved by the FDA, and manufacturers of liquid-based Pap tests, such as Hologic, Inc. (formerly Cytoc Corp.) and Beckton Dickinson and Company (formerly TriPath Imaging).

With respect to our other diagnostic t