

QIAGEN NV  
Form 20-F  
April 19, 2005  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 20-F**

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

OR

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-28564

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# QIAGEN N.V.

(exact name of registrant as specified in its charter)

**The Netherlands**

(Jurisdiction of incorporation or organization)

**Spoorstraat 50**

**5911 KJ Venlo**

**The Netherlands**

**011-31-77-320-8400**

(Address of principal executive offices)

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

**None**

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

**Title of class:**

**Common Shares, par value EUR .01 per share**

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

**None**

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The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2004 was 147,020,207.

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 which financial statement item the registrant has elected to follow.  Item 17  Item 18

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Exhibit Index located on sequential page 105.

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

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Our name together with our logo is registered as a trademark in The Netherlands, the United States and a number of other countries: QIAGEN®. Other trademarks registered in the United States 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®, EverGene®, ProofStart®, FlexiGene®, QuantiTect®, DNAprotect®, and LiquiChip®. Registered trademarks in countries outside of the United States include: QIAexpress®, QIAwell®, QIABRANE, QIAEX®, QIAprep®, QIAamp®, QIAquick®, Oligotex®, RNeasy®, BIOROBOT®, ENDOFREE®, R.E.A.L.®, PolyFect®, SuperFect®, DNeasy®, UltraFect®, HotStarTaq®, EFFECTENE®, QIA®, DyeEx®, Omniscript®, Sensiscript®, HiSpeed®, Targetene®, TransMessenger®, MagAttract®, DirectPrep®, InhibitEX®, DoubleTag®, QuantiScript®, UltraSens®, ProofTaq, pAlliance®, MinElute®, EverGene®, ProofStart®, FlexiGene®, QuantiTect®, VARISPAN, RNAprotect®, DNAprotect®, LiquiChip®, CryoCell®, LabelStar™, ROSYS, RNAiFect, Easylabel and EasyXpress. In 2004 four trademark applications were filed in Germany, Countries of the European Community, Japan and the United States of America for BioSprint, AllPrep, and Qproteome.

KingFisher® is a registered trademark of Thermo Electron Corp. GeneChip® is a registered trademark of Affymetrix, Inc.

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

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**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 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 25, 2005, was \$1.2954 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, 2004, 2003 and 2002 and the consolidated balance sheet data at December 31, 2004 and 2003 are derived from the Consolidated Financial Statements of QIAGEN which have been audited by Ernst & Young LLP, an independent registered public accounting firm, and are included herein. The selected consolidated statements of income data presented for the years ended December 31, 2001 and 2000, and the consolidated balance sheet data as of December 31, 2002, 2001 and 2000, is derived from audited consolidated financial statements not included herein.

**Selected Financial Data (amounts in thousands, except per share data)**

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

	Year Ended December 31,				
	2004	2003	2002	2001	2000
<b>Consolidated Statement of Income Data:</b>					
Net sales	\$ 380,629	\$ 351,404	\$ 298,607	\$ 263,770	\$ 216,802
Cost of sales	125,658	118,786	96,508	79,673	65,436
Cost of sales acquisition and restructuring related	1,454	3,618			
Gross profit	253,517	229,000	202,099	184,097	151,366

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Operating Expenses:					
Research and development	35,767	31,789	28,177	26,769	23,372
Sales and marketing	87,506	83,005	75,086	64,830	54,931
General and administrative	41,715	42,269	42,030	36,022	31,177
Relocation and restructure costs	3,817	3,048	10,773		
Acquisition and related costs	572		2,848	3,000	5,353
	<u>169,377</u>	<u>160,111</u>	<u>158,914</u>	<u>130,621</u>	<u>114,833</u>
Total operating expenses					
Income from operations	84,140	68,889	43,185	53,476	36,533
	<u>84,140</u>	<u>68,889</u>	<u>43,185</u>	<u>53,476</u>	<u>36,533</u>
Other income (expense), net	(11,453)	(1,634)	(4,325)	2,847	2,591
	<u>(11,453)</u>	<u>(1,634)</u>	<u>(4,325)</u>	<u>2,847</u>	<u>2,591</u>
Income before provision for income taxes and minority interest	72,687	67,255	38,860	56,323	39,124
Provision for income taxes	23,982	24,405	15,723	21,896	18,085
Minority interest (income) expense			(5)	8	36
	<u>72,687</u>	<u>67,255</u>	<u>38,860</u>	<u>56,323</u>	<u>39,124</u>
Net income	\$ 48,705	\$ 42,850	\$ 23,142	\$ 34,419	\$ 21,003
	<u>\$ 48,705</u>	<u>\$ 42,850</u>	<u>\$ 23,142</u>	<u>\$ 34,419</u>	<u>\$ 21,003</u>
Basic net income per common share(1)	\$ 0.33	\$ 0.29	\$ 0.16	\$ 0.24	\$ 0.15
	<u>\$ 0.33</u>	<u>\$ 0.29</u>	<u>\$ 0.16</u>	<u>\$ 0.24</u>	<u>\$ 0.15</u>
Diluted net income per common share(1)	\$ 0.33	\$ 0.29	\$ 0.16	\$ 0.24	\$ 0.14
	<u>\$ 0.33</u>	<u>\$ 0.29</u>	<u>\$ 0.16</u>	<u>\$ 0.24</u>	<u>\$ 0.14</u>
Weighted average number of common shares used to compute basic net income per common share	146,658	145,832	144,795	142,962	142,040
Weighted average number of common shares used to compute diluted net income per common share	148,519	147,173	145,787	145,055	145,071



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(1) Computed on the basis described for net income per common share in Note 3 of the Notes to Consolidated Financial Statements .

	December 31,				
	2004	2003	2002	2001	2000
<b>Consolidated Statement of Income Data:</b>					
Cash and cash equivalents	\$ 196,375	\$ 98,993	\$ 44,893	\$ 56,460	\$ 24,008
Working capital	\$ 299,029	\$ 163,583	\$ 111,554	\$ 119,448	\$ 101,527
Total assets	\$ 714,599	\$ 551,930	\$ 454,511	\$ 356,968	\$ 240,893
Total long-term liabilities, including current portion	\$ 234,138	\$ 131,095	\$ 112,331	\$ 88,333	\$ 29,320
Total shareholders' equity	\$ 400,376	\$ 334,786	\$ 263,031	\$ 212,975	\$ 167,356
Common shares	\$ 1,495	\$ 1,485	\$ 1,478	\$ 1,458	\$ 1,450
Shares outstanding	147,020	146,218	145,534	143,464	142,548

**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 may, will, could, expect, anticipate, estimate, continue or other similar 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 or the expansion of our operations could adversely affect our business.**

Our business has grown rapidly, with total net revenues increasing from \$216.8 million in 2000 to \$380.6 million in 2004. In 2002, we opened a research and manufacturing facility in Germantown, Maryland and manufacturing and administration facilities in Germany. In 2003 and 2004 as part of a restructuring of our U.S. operations, we relocated certain administrative, sales and marketing functions to our Maryland facility. The expansion of these facilities 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

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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. 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, 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 successfully, and any inability to do so could have a material adverse effect on our results of operations.

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### **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, 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. Acquisitions would expose us to the risks associated with the:

assimilation of new technologies, operations, sites and personnel;

diversion of resources from our existing business and technologies;

inability to generate revenues to offset associated acquisition costs;

inability to maintain uniform standards, 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.**

The market for certain of our products and services is only about fifteen years old. Rapid technological change and frequent new product introductions are typical in this market. 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 and introduce new products could reduce our growth rate or otherwise damage 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 life sciences research, 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 product relative to competitive products;

customers' opinions of the products' utility;

citation of the product in published research; and

general trends in life sciences research, applied testing 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.

**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, timing of our

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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.

### **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, 2004, we owned 60 issued patents in the United States, 37 issued patents in Germany and 225 issued patents in other major industrialized countries. In addition, at December 31, 2004, we had 256 pending patent applications and we intend to file applications for additional patents as our products and technologies are developed. However, 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.

Certain of our products incorporate patents and technologies that are licensed from third parties. 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.

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.

### **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 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

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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

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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.

### **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. 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.

### **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 and sales promotions are often made in this period. 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.

### **Competition in the Life Sciences market could reduce sales.**

Our primary competition stems from traditional separation, purification and handling methods ( traditional methods or home-brew methods ) that utilize widely available reagents and other chemicals. The success of our business depends in part on the continued conversion of current users of such traditional methods to our nucleic acid separation and purification 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 pre-analytical products and other products we offer. The markets for certain of our products are very competitive and price sensitive. Other life science research 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.

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We believe that customers in the preanalytical solutions market 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



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purchased products from competitors. To the extent we are unable to be the first to develop and supply new products, our competitive position will 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 negatively impacted 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 industry has 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 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 our products and consequently require overnight delivery of purchases. Consequently, we heavily rely on air cargo carriers such as DHL, FedEx and UPS. If overnight services are suspended or delayed and other delivery carriers cannot provide satisfactory services, customers may suspend a significant amount of work requiring pre-analytical solutions. If there are no adequate delivery alternatives available, sales levels could be negatively affected.

### **We depend on suppliers and if shipments from these suppliers is delayed or interrupted, we will 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 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 corporate 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

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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 and the United States, and our instrumentation facility is located in Switzerland. We also have established sales subsidiaries in Japan, the United Kingdom, France, Switzerland, Australia, Canada, Austria, The Netherlands and Italy. In addition, our products are sold through independent distributors serving more than 40 other countries. We began production of certain of our consumable products in the United States at our facility in Germantown, Maryland in the second quarter of 2002. We operate U.S. facilities in West Chester, Pennsylvania (sales and research and development) and Valencia, California (customer service and technical service). We also operate a research and development facility in Oslo, Norway. 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 and European subsidiaries.

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 the above conditions, an inability to successfully manage our international operations could have a material adverse impact on our operations.

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

Effective January 1, 2004 we restructured our management and formed an Executive Committee comprised of our most senior executives responsible for core functions. Dr. Metin Colpan, our former Chief Executive Officer, has transitioned his role to Senior Technology Advisor and has also joined our Supervisory Board. Mr. Peer Schatz, our former Chief Financial Officer, has taken the role of our Chief Executive Officer and Chairman of the Executive Committee. The loss of Mr. Schatz or any of our Managing Directors or Deputy Managing Director could have a material adverse effect. 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 future 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 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 commercially reasonable terms, 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;

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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 or other existing resources. 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.

**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 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.

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

At December 31, 2004, 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 pay 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.

**Changing government regulations may adversely impact our business.**

QIAGEN 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,

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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.

Additionally, 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.

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 and clinical trials and other regulatory clearance. Such trials will be subject to extensive regulation by governmental authorities in the United States and other countries 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. Our failing to obtain such clearance or approvals can significantly damage our business in such segments.

Since the European Union Directive 98/79/EC on in vitro diagnostic medical devices went into effect on December 7, 2003, all products and kits which are used for in vitro diagnostic applications and which are sold after this date have to be compliant with this European 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), pre-analytical solutions, including nucleic acid purification products, which are used in diagnostic workflows are affected by this new 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.

### **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 payers are increasingly seeking to contain health care 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, of QIAGEN itself, could be adversely affected.

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

The marketing and sale of certain 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





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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.

### **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 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. The lending arrangements entered into by QIAGEN GmbH with a group of banks led by Deutsche Bank in 2001 and amended in July 2004 limits the amount of distributions that can be made by QIAGEN GmbH to QIAGEN N.V. during the period the borrowings are outstanding. The portion of this facility that would otherwise expire in October 2005 was repaid out of new borrowings in the third quarter of 2004. The remaining portion of this facility will expire in annual installments through June 2011. 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.

### **Risks Related to Our Common Shares**

#### **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 past two fiscal years, the closing price of our common shares has ranged from a high of \$15.61 to a low of \$5.20 on the NASDAQ National Market System, and a high of EUR 12.40 to a low of EUR 4.93 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;

changes in government regulations or patent laws;

developments in patent or other proprietary rights;

developments in government spending for life sciences related research; and

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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 are not expected to receive dividend income.**

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

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**Shareholders who are United States residents could be subject to unfavorable tax treatment.**

We may be classified as a passive foreign investment company ( PFIC ) for U.S. federal income tax purposes if certain tests are met. Our treatment as a PFIC could result in a reduction in the after-tax return to the holders of common shares and would likely cause a reduction in the value of such shares. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to our U.S. shareholders. We would be considered a PFIC with respect to a U.S. shareholder if for any taxable year in which the U.S. shareholder held the common shares, either (i) 75% or more of our gross income for the taxable year is passive income; or (ii) the average value of our assets (during the taxable year) which produce or are held for the production of passive income is at least 50% of the average value of all assets for such year. Based on our current income, assets and activities, we do not believe that we are currently a PFIC. No assurances can be made, however, that the IRS will not challenge this position or that we will not subsequently become a PFIC.

**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. As of December 31, 2004, we had outstanding 147,020,207 common shares plus 13,047,739 additional shares subject to outstanding stock options, of which 9,479,000 were then exercisable. A total of approximately 18.6 million common shares are reserved for issuances under our stock option plan, including those shares subject to outstanding stock options. 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. are entitled to convert their Notes into approximately 11.9 million common shares, although the resale of these common shares would be subject to some restrictions.

**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 (the 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 representing more than 50 percent of the outstanding shares. They also provide that if the members of our Supervisory Board and our Managing Board have been nominated by the Supervisory Board and Managing Board, shareholders may only overrule this nomination with a vote of two-thirds of the votes cast representing more than 50 percent of the outstanding 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 shares by issuing preference shares. Pursuant to these provisions (and pursuant to the resolution adopted by our general meeting on July 16, 2004), our Supervisory Board is authorized to issue preference shares or grant rights to subscribe for preference shares if (i) a person has (directly or indirectly) acquired or has expressed a desire to acquire, more than 20 percent of our issued share capital, or (ii) a person holding at least a ten percent interest in our share capital has been designated as a hostile person by our 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.

We have also recently granted an option to a 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 less one share. When exercising the option and exercising its voting rights on such shares, the Foundation has to 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.

**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, our officers

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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 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*

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 for our wholly owned subsidiaries. Our legal seat is in Venlo, The Netherlands. As a holding company, we conduct our business through our subsidiaries located throughout Europe, Japan, Australia, Canada and the United States. Our principal executive office is located at Spoorstraat 50, 5911 KJ Venlo, The Netherlands, and our telephone number is +31-77-320-8400. Our website is [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. We have experienced significant growth in the past, with a five year compound annual growth through December 31, 2004 of approximately 19% in net sales and 29% in net income, as reported under U.S. GAAP. In the last five years we have made a number of strategic acquisitions and have also restructured some of our key operations. Significant events in the development of our business in 2004 include:

The completion of the relocation of our North American marketing and sales operations from Valencia, California to Germantown, Maryland in order to utilize the capacity of our North American Headquarters. As a result, we incurred \$3.8 million in relocation and restructuring costs in 2004.

The sale of the majority of our synthetic DNA business unit in the second quarter of 2004. As a result we recorded a net loss related to the sale of \$9.8 million to other miscellaneous expense.

The acquisition of the technology and product portfolio of Molecular Staging, Inc. in the third quarter of 2004. As a result, we recorded a \$1.5 million charge to cost of sales for a write-down of inventories, which will be replaced with products integrating newly acquired technologies, and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition.

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The establishment of QIAGEN Finance S.A. (QIAGEN Finance), an unconsolidated subsidiary located in Luxembourg, for the purpose of issuing convertible debt. In August 2004, we issued \$150.0 million

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of 1.5% Senior Convertible Notes due in 2024 (the Notes) through QIAGEN Finance, and in turn the proceeds were loaned to subsidiaries within the consolidated QIAGEN N.V. group. QIAGEN N.V. has guaranteed the Notes, and has an agreement with QIAGEN Finance to issue shares to the investors in the event of conversion.

The opening of a new subsidiary in The Netherlands which directly supplies QIAGEN's complete range of integrated solutions, services, technical support, and online ordering facilities to our customers in the Benelux region.

Capital expenditures for property, plant and equipment totaled \$12.6 million, \$19.6 million, and \$59.1 million for the years ended December 31, 2004, 2003 and 2002. Capital expenditures during the year ended December 31, 2002 consisted principally of the purchases of property and equipment in connection with the expansion of our production operations in the United States and Germany. The capital investment programs were completed at the end of 2002, and as a result, the cash flow required for capital investing decreased in 2003 and 2004.

## **Business Overview**

### *Description of Our Business*

We believe that we are the world's leading provider of innovative enabling technologies and products for the separation, purification and handling of nucleic acids (DNA/RNA). This belief is based on the nature of our products and technologies and on our United States and European market shares as supported by independent market studies. We also manufacture and market a range of other solutions for pre-analytical sample processing and handling, as well as, synthetic nucleic acids (RNAi) and related services and products. Additionally, we sell and/or license technologies to others. We operate exclusively in life sciences-related industries, and develop, manufacture and market a broad portfolio of proprietary technologies and products, which meet the needs of the markets including academic and industrial research, applied testing and molecular diagnostics. Our products enable customers to reliably and rapidly process samples from collection through to purification of the target molecule, such as nucleic acids or proteins, without using hazardous reagents or expensive equipment.

We have developed or acquired a core set of technologies to provide a comprehensive approach to pre-analytical sample handling, separation and purification. These technologies can be used alone or in combination to achieve the best solution for a given application. In particular, our proprietary technologies for magnetic particle-based purification, solid-phase anion-exchange purification and selective adsorption to silica particles or membranes significantly enhance nucleic acid purification, the most difficult, critical, and labor intensive step in nucleic acid isolation. We believe that our technologies represent substantial advances in the speed, reliability, and ease of use of nucleic acid separation and purification procedures and the purity and yield of the resulting nucleic acids.

### *Our Products*

We offer over 300 products for a variety of applications in the handling, separation, purification, and subsequent use of nucleic acids and proteins. 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:* We offer most of our consumable products in kit form to maximize customer convenience and reduce user error. These kits contain our proprietary disposable handling, separation and purification devices and/or other proprietary technologies, all

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necessary reagents and buffers, and a technical handbook that includes a detailed protocol and background information. Each kit includes devices and reagents for a number of preparations ranging from one to thousands. Each kit is covered by our quality guarantee. Major applications for our consumable products are plasmid DNA purification; RNA stabilization and purification; genomic and viral nucleic acid purification; nucleic acid transfection; PCR amplification; reverse transcription; DNA cleanup after PCR and sequencing; DNA cloning and protein purification.



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*Instrumentation:* Our BioRobot systems offer walk-away automation of nucleic acid preparation in low, medium or high throughput scale, as well as reaction set-up and other laboratory tasks.

*Services:* We also offer custom services, siRNA synthesis, whole genome amplification services, DNA sequencing, and non-cGMP and cGMP DNA production on a contract basis.

## ***Research and Development***

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.

Our research and development organization is matrix structured and is overseen by our Senior Vice President of Research & Development. We conduct most of our research and development activities in Germany, Switzerland, Norway and the U.S. Our organization structure allows us flexibility to refocus our product development efforts as new technologies or markets emerge. The total number of research and development employees at December 31, 2004 was 276. Our total research and development expenses in 2004, 2003 and 2002 were approximately \$35.8 million, \$31.8 million, and \$28.2 million, respectively. In 2004 we introduced several significant new products, including:

a strategically important new product line for protein sample preparation which positions us as a leading provider for proteomic sample fractionation kits. This Qproteome product line is believed to represent one of the broadest, most comprehensive and technologically most advanced solution portfolios for the fractionation and depletion of proteins. The Qproteome product line can be used in parallel to and in combination with nucleic acid sample preparations and analysis products.

the first worldwide CE-marked stand alone automated sample preparation system for viral nucleic acids. The BioRobot MDx DSP instrument and the QIAamp DSP 96 Virus MDx Kit are the first of their kind in the molecular diagnostics marketplace.

the launch of the first set of manual CE-marked kits, QIAamp DSP Virus Kit and QIAamp DSP DNA Blood Mini Kit for isolation of viral nucleic acid and genomic DNA from blood, respectively.

a suite of instruments and consumables based on our exclusive agreement to co-market and co-promote Thermo Electron's (NYSE: TMO) KingFisher® instrumentation technology together with our magnetic bead based nucleic acid separation and purification technologies for use in nucleic acid-based applications.

the BioRobot Gene Expression GeneChip® Target Prep System which is a complete automated solution for preparing labeled cRNA targets for use with arrays such as Affymetrix GeneChip arrays. By automating the steps from first-strand cDNA synthesis to fragmentation of cRNA, the system both saves hands-on time and standardizes the preparation of cRNA targets, enabling more precise GeneChip array results.

## ***Sales and Marketing***

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We market our products in more than 40 countries throughout the world. We have subsidiaries in the markets that we believe have the greatest sales potential the United States, Germany, the United Kingdom, Switzerland, France, Japan, Australia, Canada, Norway and Italy. We have established a network of highly experienced marketing personnel and employ a dedicated field sales force of over 400 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 serving more than 30 countries.

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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 inform them of new product offerings. 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 without charge. 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. 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 *Nature*, *Science*, and *BioTechniques*, 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 a personalized bi-monthly electronic newsletter for our worldwide customers that provides 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. We also have a Japanese language site ([www.qiagen.co.jp](http://www.qiagen.co.jp)) and some information is available on our website in French and German to support these local markets.

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 can be an effective barrier to competitor entry, while also reducing distribution costs and increasing our visibility in the laboratory.

### ***Principal Markets***

From our inception, we have believed that nucleic acids 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 handling, separation and purification of nucleic acids since 1986. Customers include major academic institutions and governmental laboratories such as the United States National Institutes of Health (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, and applied testing such as forensics, veterinary diagnostics, genetically modified organisms (GMO) and other food testing. 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 390,000 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 early on 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 300 nucleic acid handling, separation and purification products to customers. We also offer innovative protein expression and purification products. 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

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laboratories continue to convert from traditional methods to our products. 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. 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.

### ***Nucleic Acid-Based Molecular Diagnostics Market***

We believe that the molecular diagnostics market represents a significant market for nucleic acid separation and purification products. We believe that the advent of PCR and other amplification technologies has made the prospect of nucleic acid-based molecular diagnostics feasible. Nucleic acid-based molecular diagnostics have fundamental advantages over traditional diagnostic technologies such as immunoassays in both specificity and sensitivity. 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 must be amplified to facilitate detection. Potential commercial applications for nucleic acid-based molecular diagnostics include infectious disease diagnostics in blood 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.

The success of nucleic acid-based 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. The QIAGEN BioRobot 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 the BioRobot EZ1, BioRobot M48/96, BioRobot 9604 and BioRobot MDx are ready for use in the demanding and sensitive downstream assays performed in molecular diagnostic applications. In order to broadly address the market for nucleic acid preparation in molecular diagnostics, we are entering into partnerships or other agreements with established companies in the molecular diagnostics market.

### ***Applied Testing Market***

We believe that emerging applied testing markets such as forensics, veterinary and food, offers great opportunities for standardized sample preparation, modification and detection solutions. Successes in crime cases due to DNA analyses, public debates about genetically modified organisms (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 as well as 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.

### ***Genetic Vaccination and Gene Therapy Market***

We believe that the potential use of nucleic acids as vaccines or drugs represents the largest untapped market for nucleic acid separation and purification products. Analysis of data from the Human Genome Project should result in the identification of genes and gene mutations that are responsible for many common diseases and conditions, such as cancer, coronary artery disease, asthma, and obesity. Scientists believe that these discoveries may lead to the development of a new generation of drugs, based either on the delivery of non-mutated genes to prevent or cure disease, or on the development of therapeutics which can mimic the biological functions of genes. A further application, which may emerge

from ongoing gene research, is the development of

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genetic vaccination. Studies suggest that vaccination against diseases may be more effective using nucleic acid fragments from the disease-causing organisms rather than conventional vaccination approaches using recombinant proteins or the inactivated infectious agent. The commercialization of these drugs and vaccines will depend on the availability of large-scale production of ultrapure nucleic acids. We believe that the use in clinical testing of nucleic acids purified using our technologies and products will give us a strong position in this market once genetic vaccination and gene therapy products become commercially available.

**Seasonality**

Our business does not experience specific 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 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 our subsidiary as certain subsidiaries have international distribution. See Note 20 to our consolidated financial statements included in Item 18. Financial Statements for additional information with respect to operations by geographic region.

Net Sales	2004	2003	2002
Germany*	<b>\$ 163,841,000</b>	\$ 153,143,000	\$ 136,334,000
United States*	<b>271,107,000</b>	261,366,000	221,762,000
Switzerland*	<b>37,936,000</b>	34,916,000	30,953,000
Japan*	<b>41,563,000</b>	46,839,000	34,937,000
United Kingdom	<b>31,511,000</b>	24,651,000	19,252,000
Other Countries*	<b>55,957,000</b>	48,146,000	29,730,000
Subtotal	<b>601,915,000</b>	569,061,000	472,968,000
Intersegment Elimination+	<b>(221,286,000)</b>	(217,657,000)	(174,361,000)
Total	<b>\$ 380,629,000</b>	\$ 351,404,000	\$ 298,607,000

\* 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 do not depend 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. Therefore, we consider the protection of our proprietary technologies and products for the separation and purification of nucleic acids 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 60 issued patents in the United States, 37 issued patents in Germany and 225 issued patents in other major industrialized countries, and have 256 pending patent applications. Worldwide, we own 322 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

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other countries have a term of 20 years from the date of filing of 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 and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting 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 QIAGEN 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 subject to other specific exceptions. In the case of employees, the agreements provide that all inventions conceived by the individual while employed by us 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 complement or expand our business, we also intend to continue to make strategic investments in or acquisitions of complementary businesses and technologies as the opportunities arise.

### ***Competition***

We believe that our primary competition stems from 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 nucleic acid separation and purification products in kit form and reagents for PCR and transfection. Competitors include: Promega Corp., Millipore Corp., Roche Diagnostics, Invitrogen Corp. and Macherey-Nagel GmbH for nucleic acid separation and purification; Applied Biosystems, Invitrogen Corp. and Promega Corp. for PCR reagents; Invitrogen Corp. and Promega Corp. for transfection reagents, 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 believe that our competitors do not have the same comprehensive approach to pre-analytical solutions, including to nucleic acid handling, separation and purification and therefore cannot provide the broad range of technologies and depth of products and services that we offer. With our complete range of manual and fully automated solutions, we offer the value of standardization of procedures and therefore superior results.



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Our continued future success will rely in large part on our ability to maintain our technological advantage over competing products, expand our market presence and preserve customer loyalty. There can be no assurance that we will be able to compete effectively against our existing or future competitors or that developments by others will not render our technologies or products non-competitive.

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### ***Suppliers***

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. Raw materials generally include chemicals, raw separation media, biologics, plastics and packaging. Raw materials are generally readily available at competitive, stable prices from a number of suppliers. Certain raw materials are produced under our specifications, so we closely monitor stock levels to maintain adequate supplies. We believe we maintain raw materials at a level to ensure reasonable customer service levels, and to guard against normal volatility in the availability.

### ***Government Regulations***

We are not subject to direct regulation other than regulation generally applicable to businesses pursuant to various laws and regulations in effect in the different jurisdictions in which we operate, including laws and regulations applicable to environmental matters, such as the handling and disposal of hazardous wastes. Our research and development activities involve the controlled use of small amounts of hazardous materials, chemicals and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by applicable regulations, such as the United States Occupational Safety and Health Administration's (OSHA) Hazard Communication and Occupational Exposure to Hazardous Chemicals in Laboratories standards, 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.

We also comply with the OSHA Bloodborne Pathogens standard and the Center for Disease Control/National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories standards for the handling of biological materials as well as comply with the United States Department of Transportation and International Air Transport Association regulations for the shipping of our kits which contain materials classified as hazardous. There are other federal, state and local laws and regulations applicable to our business, including those of the United States Environmental Protection Agency and the Maryland Department of the Environment. However, we do not expect that compliance with governmental regulations to which we are subject will have a material effect on our capital expenditures, earnings or competitive positions.

Sales volumes of certain of our products in development may be dependent on commercial sales by our customers of diagnostic and pharmaceutical products, which will require preclinical studies and clinical trials and other regulatory requirements. Trials will be subject to extensive regulation by governmental authorities in the United States, including the Food and Drug Administration (FDA) and equivalent agencies in other countries, and involve substantial uncertainties. In addition, certain of our products, especially products intended for use in in-vitro diagnostics applications, are dependent on regulatory or other clearance. Our failing to provide such clearance or approvals can significantly damage our business in such segments.

### ***Organizational Structure***

QIAGEN N.V. is the holding company for 22 consolidated subsidiaries, the majority of which have the primary function of the distribution of our products and services on a regional basis. Certain subsidiaries also have research and development or production activities. A listing of our significant subsidiaries, all of which are wholly owned, and their country of incorporation, is included in Exhibit 8.1 to this Annual Report.

### ***Description of Property***

Our production and manufacturing facilities for consumables products are located in Germantown, Maryland, Hilden and Erkrath, Germany. The instrument production facility is located at the QIAGEN Instruments AG facility in Hombrechtikon, Switzerland and was expanded in 2003. Over the last several years, we have made investments in automated and interchangeable production equipment to increase our production capacity and improve efficiency. For GMP production, special GMP areas were built in our facilities at Hilden

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and Erkrath. Our production and manufacturing operations are highly integrated and benefit from sophisticated inventory control. We have also installed and continue to expand production-planning systems that are included in our integrated information and control system based on the business software package SAP R/3 from SAP AG. Worldwide, SAP integrates our material operating subsidiaries. Our production management personnel are highly qualified and many have engineering degrees.

The consumable products manufactured at QIAGEN GmbH are produced under ISO 9001:1994/EN 46001:1996 standards; we received our certification in January 1999. QIAGEN Instruments AG which produces the majority of our BioRobot® instrumentation product line received ISO 9001 certification in May 1997. Our ISO 9001 and EN 46001 certifications form part of our ongoing commitment to providing our customers high quality, state-of-the-art products and technologies for the handling, separation and purification of nucleic acids and proteins and to the development of our Total Quality Management system.

Our facilities in Hilden, Germany currently occupy approximately 221,000 square feet, some of which is leased pursuant to separate contracts expiring between the years 2004 and 2018. In two separate transactions between July 1997 and February 1998, QIAGEN purchased a parcel of land directly adjacent to our existing German facilities, measuring approximately 549,000 square feet. During 2003, we completed a 115,000 square foot production facility and a 149,000 square foot administration building on this land at a cost of EUR 55.4 (approximately \$69.8 million). QIAGEN also leases cGMP production facilities in Germany.

We increased our production capacity with the establishment of a manufacturing and research facility in the United States. In 1999, QIAGEN Sciences, Inc. purchased of an 18-acre site for approximately \$3.2 million in Germantown, Maryland. Construction began in March 2000, and in November 2000 QIAGEN Sciences exercised the option to purchase an additional adjacent lot of approximately 6 acres for \$1.2 million. The purchase of this additional lot allows for future expansion of up to 400,000 square feet of additional facility space. Construction was financed primarily by intercompany loans and long-term bank debt. Early in 2002, construction on the manufacturing portion of the facility was completed at a cost of approximately \$57.5 million. The 200,000 square foot Maryland facility consists of several buildings in a campus-like arrangement and is intended to accommodate over 300 employees. Construction of siRNA/RNA research and development lab and production space, as well as additional office space, was completed in the first quarter of 2003 at a cost of approximately \$3.9 million. QIAGEN Sciences is integrated with our other North American and European subsidiaries through our SAP business information systems and utilizes production-planning, quality management and inventory management modules from SAP in order to increase efficiency.

Our corporate headquarters are located in leased office space in Venlo, The Netherlands. Other subsidiaries throughout the world lease small amounts of space.

We believe that our existing production and distribution facilities can support our planned production needs for the next 36 months. Our production and manufacturing operations are subject to various federal, state, and local laws and regulations including environmental regulations. We believe we do not have any material issues relating to these laws and regulations.

### **Item 5. Operating and Financial Review and Prospects**

*This section contains a number of forward-looking statements. These statements are based on current management expectations, and actual results may differ materially. Among the factors that could cause actual results to differ from management's expectations are those described in Risk Factors above, and Business Factors below.*

***Business Factors***

This report contains forward-looking statements that are subject to certain risks and uncertainties. These statements can be identified by the use of forward-looking terminology such as may, will, could, expect, anticipate, estimate, continue or other similar words. Such statements are based on management's current

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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, including, but not limited to, the following: risks associated with our expansion of operations, including the acquisition of new companies; variability in our operating results from quarter to quarter; management of growth, international operations, and dependence on key personnel; intense competition; technological change; our ability to develop and protect proprietary products and technologies and to enter into collaborative commercial relationships; our future capital requirements; general economic conditions and capital market fluctuations; and uncertainties as to the extent of future government regulation of our business. As a result, our future development efforts involve a high degree of risk. For further information, refer to the more specific risks and uncertainties discussed under the caption "Risk Factors" in Item 3 and throughout this Form 20-F.

## ***Results of Operations***

### *Overview*

We produce and distribute biotechnology products, primarily for the handling, separation and purification of biological samples prior to their analysis (pre-analytical processing). A substantial portion of our sales come from products that address the pre-analytical processing of nucleic acids (DNA/RNA). In addition, we sell PCR- and siRNA- related products and services, as well as license and sell technology or the rights to it. We believe that we are the world's leading provider of innovative enabling technologies and products for nucleic acid handling, separation and purification, based on the nature of our products and technologies and on our United States and European market shares as supported by independent market studies. We operate exclusively in the life sciences industry, and develop, manufacture and market a broad portfolio of proprietary technologies and products to meet the needs of the academic and industrial research, applied testing and molecular diagnostics markets. Our products enable customers to reliably and rapidly produce high purity nucleic acids without using hazardous reagents or expensive equipment.

We segment our business based on the geographic locations of our subsidiaries. Our reportable segments include Germany, the United States, Switzerland, Japan, the United Kingdom, Norway and Other Countries (consisting of subsidiaries in Canada, France, Australia, Italy, Austria and The Netherlands, which services Belgium, The Netherlands and Luxembourg). Our research, production and manufacturing facilities are located in Germany, the United States, Switzerland and Norway. Our holding company is located in The Netherlands. Reportable segments derive revenues from our entire product and service offerings. Our Luxembourg subsidiary, QIAGEN Finance, which was established as the financing vehicle for the issuance of convertible debt, is not consolidated.

Since 1999, we have had compound annual growth of approximately 19% in net sales and 29% in net income based on reported U.S. GAAP results. In recent years we have made a number of strategic acquisitions and disposals expanding and focusing our technology and product offerings. These transactions include:

In September 2004, we completed the acquisition of key assets of Molecular Staging, Inc. (MSI) of New Haven, Connecticut. MSI was a privately held company which had developed a range of proprietary products and services based on its Multiple Displacement Amplification (MDA) and Rolling Circle Amplification (RCAT) technology. The key application of MDA is whole genome amplification (WGA) which is designed to eliminate limitations created by the scarce quantities of DNA samples available for customers to perform an increasing number of analyses. The technology portfolio acquired from MSI adds a new dimension of customer benefit and is in our core focus on pre-analytical solutions. The primary reason for the acquisition was to enable us to provide customers a solution for overcoming the limitations of scarce DNA samples.

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In June 2004, we sold a significant portion of our synthetic DNA business unit to a group of investors since the market dynamics and strategic directions this business were becoming different in nature

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compared to our core focus. We retained all rights and activities in our leading siRNA business including ownership of our proprietary TOM-amidite chemistry.

In June 2002, we completed the acquisition of GenoVision A.S. located in Oslo, Norway. GenoVision A.S. was formed in 1998 and had two wholly owned subsidiaries and one majority owned subsidiary. We believe that the acquisition has provided us with unique, automated solutions for the purification of nucleic acids based on GenoVision's proprietary magnetic particle technologies.

In April 2002, we completed the acquisition of Xeragon, Inc. of Huntsville, Alabama. Established in 2001, Xeragon is a market and technology leader for products and services focusing on synthetic nucleic acids, particularly siRNA.

In 2002 we completed our North American Headquarters in Germantown, Maryland and also completed production and office facilities in Hilden, Germany. In December 2002, we closed the QIAGEN Genomics facility located in Bothell, Washington and relocated certain activities to our recently opened facilities in Germantown, Maryland and Hilden, Germany. In December 2003, we committed to a relocation and restructure plan to more fully utilize our North American Headquarters in Germantown, Maryland and to discontinue certain products. This plan was completed in 2004.

To date, we have funded our growth through internally generated funds, debt and private and public sales of equity securities.

On a consolidated basis, operating income increased to \$84.1 million in 2004, compared to \$68.9 million in 2003. The increase in operating income is primarily the result of increased sales and lower operating costs as a result of our recent restructuring efforts, partially offset by acquisition related costs and costs related to our restructuring and relocation efforts. Further, 2003 operating income includes the results of our former synthetic DNA business unit a significant portion of which was sold at the end of the second quarter in 2004. Accordingly, the last six months of 2004 does not include any sales of synthetic DNA and related products or operating costs related to the former business unit.

On a comparative basis sales increased primarily as the result of an increase in our consumables products sales, which experienced very solid growth in 2004 compared to 2003. During 2004, we continued in our plans to realign certain operating functions in line with our focus on streamlining and strengthening our operations. In 2004, we recorded charges of \$3.8 million, respectively, related to our restructuring and relocation efforts. Upon the acquisition of the key assets of MSI, we recorded costs related to the acquisition in the third quarter of 2004 including a \$1.5 million charge to cost of sales for a write-down of inventories, which will be replaced with products integrating newly acquired technologies, and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition. Further, on a comparative basis, operating income during 2004 was negatively impacted by the currency impact of the stronger euro, since a significant portion of our production and operations is based in Germany, along with lower gross margins from instrumentation sales. After the sale of a significant portion of our synthetic DNA business unit, our gross margin is no longer negatively impacted by such products and as a result, our reported gross margin in 2004 increased to 67% compared to 65% for the same period in 2003.

The following tables set forth summaries of operating income by segment for the years ended December 31. More complete tables can be found in Note 20 in the accompanying financial statements.

Operating Income (Loss)	2004	2003
Germany	\$ 28,670,000	\$ 22,355,000
United States	36,473,000	32,641,000
Switzerland	1,492,000	(798,000)



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All other segments	18,142,000	13,661,000
<b>Subtotal</b>	<b>84,777,000</b>	<b>67,859,000</b>
Intersegment Elimination	(637,000)	1,030,000
<b>Total</b>	<b>\$ 84,140,000</b>	<b>\$ 68,889,000</b>

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In Germany, operating income was higher in 2004 as compared to 2003 primarily due to increased overall gross margin as a result of increased consumable sales which have a higher gross margin, partially offset by an increase in operating costs, primarily acquisition related costs.

Operating income in the United States was positively impacted in 2004 compared to 2003 by increased sales of consumables products and by a \$4.0 million sale of technology to Operon Biotechnologies, Inc. This increase in sales was partially offset by the lack of sales of synthetic DNA and related products in the second half of 2004 following the sale of the synthetic DNA business unit in June 2004. Operating expenses in the United States were lower as a result of the recent restructuring efforts. However, the impact of lower operating costs was partially offset by increased acquisition and relocation and restructuring costs.

Operating income in Switzerland was higher in 2004 as compared to 2003 primarily due to a \$1.0 million license of software to Operon Biotechnologies, Inc. and an increase in intercompany sales.

We regularly introduce new products in order to extend the life of our existing product lines as well as to address new market opportunities. During 2004, we introduced over 30 new products, including the first worldwide CE-marked stand alone automated Sample Preparation System for Viral Nucleic Acids composed of the BioRobot MDx DSP; QIAsoft MDxDSP; the QIAamp DSP 96 Virus MDx Protocols and the QIAamp DSP 96 Virus MDx Kit. Further, the declaration of conformity to the IvDD has been obtained for the MDx DSP System which targets diagnostics markets and is approved for such marketing under the CE regime.

### ***Fiscal Year Ended December 31, 2004 compared to 2003***

#### *Net Sales*

In 2004, net sales increased 8% to \$380.6 million from \$351.4 million in 2003. Net sales in the United States increased to \$167.4 million in 2004 from \$154.4 million in 2003, and net sales outside the United States increased to \$213.2 million in 2004 from \$197.0 million in 2003.

The increase in sales was primarily the result of an increase in our consumable products sales and our BioRobot product line, which experienced strong growth in 2004 compared to 2003. Outside of the United States, the increase in net sales was primarily due to growth at QIAGEN GmbH, located in Germany, which reported an increase of 10% (\$14.7 million), QIAGEN Ltd., located in the United Kingdom, which reported an increase of 28% (\$6.9 million) and QIAGEN Instruments, located in Switzerland, which reported an increase of 17% (\$4.3 million). QIAGEN Benelux B.V., our newly established sales subsidiary serving Belgium, The Netherlands and Luxembourg regions, reported sales of \$4.4 million during 2004. Prior to the establishment of this new subsidiary, QIAGEN GmbH reported sales to the Benelux region as sales to a third-party distributor. During 2004, QIAGEN K.K., located in Japan, reported a decrease of 4% (\$1.6 million), which is partly attributable to a change in local purchasing procedures during the year. We believe the impact of this change is temporary. Further, in the second quarter 2004, we sold a significant portion of our synthetic DNA business unit. Accordingly, net sales for the second half of 2004 in the United States, Germany and Japan did not include any sales of the synthetic DNA products, which were included in the 2003 net sales.

Changes in exchange rates continued to affect the growth rate of net sales for the year ended December 31, 2004. A significant portion of our revenues is denominated in European Union euros. Using identical foreign exchange rates for both years, net sales would have increased approximately 5% as compared to the reported increase of 8% for the year ended December 31, 2003. See Currency Fluctuations.

*Gross Profit*

Gross profit was \$253.5 million or 67% of net sales in the year ended December 31, 2004 as compared to \$229.0 million or 65% of net sales in 2003. The absolute dollar increase is attributable to the increase in net sales

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partially offset by the currency impact of the stronger euro. The 2003 gross profit includes sales of our synthetic DNA business unit, a significant portion of which was sold at the end of the second quarter in 2004. Accordingly, the second half of 2004 does not include any sales of synthetic DNA and related products, which carried a lower gross profit than our consumables products, thus the reported gross profit in 2004 is higher than 2003. Further, the increase in gross profit as a percentage of net sales is also attributable to the increase in net sales of consumable products, partially offset by the currency impact of the stronger euro. Additionally, manufacturing costs incurred at our newer production facilities in Germantown, Maryland and Hilden, Germany, which began production operations in the second and fourth quarters of 2002, respectively, negatively impacted gross profit. These facilities added production capacity, which resulted in increased fixed production costs. These higher fixed costs will continue to be a cost of production in the future, though as production increases and we more fully utilize the additional capacity of these facilities, we expect that gross profit, as a percentage of sales, will increase. In connection with the acquisition of Molecular Staging, Inc. we expensed \$1.5 million of inventory to cost of sales in the third quarter of 2004, which will be replaced with products integrating the newly acquired technologies.

### *Research and Development*

Research and development expenses increased 13% to \$35.8 million (9% of net sales) in 2004 compared with \$31.8 million (9% of net sales) in 2003. Using identical foreign exchange rates for both years, research and development expenses increased approximately 8%. We expanded our German research facility late in 2002, which resulted in increased costs related to research and development starting in the first quarter of 2003. Our U.S. facility located in Germantown, Maryland now includes research and development activities, including those related to siRNA. The increase in research and development expenses is also attributable to the currency impact of the stronger euro, and was partially offset by the sale of our former synthetic DNA business unit in the second quarter of 2004. As we continue to expand our research activities and product development capabilities, additional expense will be incurred related to research and development facility costs and the employees engaged in our research and development efforts. We have a strong commitment to research and development and anticipate that absolute research and development expenses may increase significantly.

### *Sales and Marketing*

Sales and marketing expenses increased 5% to \$87.5 million (23% of net sales) in 2004 from \$83.0 million (24% of net sales) in 2003. Using identical foreign exchange rates for each year, sales and marketing expenses increased approximately 5%. Sales and marketing costs are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses and other promotional items. The decrease in sales and marketing expenses as a percentage of sales in 2004 is primarily a result of our recent restructuring and relocation efforts. We anticipate that sales and marketing costs may increase along with new product introductions and continued growth in sales of our products.

### *General and Administrative*

General and administrative expenses decreased 1% to \$41.7 million (11% of net sales) in 2004 from \$42.3 million (12% of net sales) in 2003. Using identical foreign exchange rates for both years, general and administrative expenses increased approximately 5%. General and administrative expenses primarily represent the costs required to support our administrative infrastructure which, until our recent restructuring, continued to expand along with our growth. General and administrative expenses were lower in 2004 as a result of our relocation and restructuring efforts, including the sale of our synthetic DNA business unit, which we sold at the end of June 2004.

### *Acquisition and Related Costs*

Costs related to the acquisition of Molecular Staging, Inc. in the third quarter of 2004 included a \$1.5 million charge to cost of sales for a write-down of inventories, which will be replaced with products integrating

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newly acquired technologies, and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition.

### *Relocation and Restructure Costs*

During 2004 we continued executing on our plans to realign certain operating functions in order to concentrate the locations of our activities and strengthen our operational effectiveness. In December 2003, we began the relocation of certain functions from our subsidiary in Valencia, California to our North American Headquarters located in Germantown, Maryland in order to utilize the capacity of our North American Headquarters in Germantown. In addition, in 2003 we realigned research and development programs, streamlined our product offering and discontinued certain product lines related to certain microarray-related products

As a result of the above plans, in 2004, we recognized approximately \$3.8 million in operating expenses related to employee relocation and severance costs. In 2003 we expensed approximately \$3.6 million to cost of sales for the write-down of inventories and approximately \$1.5 million to operating expenses related to relocating employees, severance for employees not relocating and the write-off of investments. These restructuring and relocation activities were completed in 2004 for a total cost of approximately \$8.9 million. Additionally, in 2003 approximately \$1.6 million of costs were incurred to complete the closure of the QIAGEN Genomics site in Bothell, Washington, mainly lease related costs.

### *Other Income (Expense)*

Other expense was \$11.5 million in 2004 compared to \$1.6 million in 2003. This increase in expense was primarily due to the sale of the majority of our synthetic DNA business unit to a group of investors including a former member of management. As a result we recorded a net loss related to the sale of \$9.8 million in the second quarter of 2004.

In 2004, research and development grant income from European as well as German state and federal government grants decreased to \$1.6 million from \$2.2 million in 2003. We conduct significant research and development activities in Germany, and expect to continue to apply for such research and development grants in the future.

We recorded a loss from foreign currency transactions of \$67,000 in 2004 as compared to a gain of \$1.1 million in 2003. The gain or loss from foreign currency transactions reflects net effects from conducting business in currencies other than the U.S. dollar. QIAGEN N.V.'s functional currency is the U.S. dollar and its subsidiaries' functional currencies are the European Union euro, the British pound, the Swiss franc, the U.S. dollar, the Australian dollar, the Canadian dollar, the Japanese yen and the Norwegian krone. See Currency Fluctuations under Item 11 Quantitative and Qualitative Disclosures About Market Risk .

For the year ended December 31, 2004, interest income increased to \$2.9 million from \$1.3 million in 2003. Interest income is derived from our investment of funds in investment grade, interest-bearing marketable securities and from cash balances. As of December 31, 2004, we had approximately \$30.2 million invested in marketable securities. The weighted average interest rates on the marketable securities portfolio ranged from 1.27% to 1.45% in 2004, compared to 1.37% to 1.46% in 2003.

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Interest expense increased to \$5.1 million in 2004 compared to \$4.6 million in 2003. Interest costs relate primarily to our long-term borrowings of the proceeds from the convertible debt offering along with the long-term debt related to our facility construction.

In 2004, we recorded net losses from equity method investees of \$2.2 million compared to \$1.8 million in 2003. The loss primarily represents our share of losses from our equity investment in PreAnalytiX. We sell certain products directly as joint venture products and certain products are sold the use of via protocols and related QIAGEN products through QIAGEN. The aggregated PreAnalytiX activities are highly profitable for

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QIAGEN. Due to the structure of the joint venture-related activities, the joint venture entity itself, PreAnalytiX GmbH, is expected to report net losses for our fiscal year 2005. As previously disclosed, we intend to continue to make strategic investments in complementary businesses as the opportunities arise. Accordingly, we may continue to record losses on equity investments in start-up companies based on our ownership interest in such companies.

Other expense was \$8.5 million in 2004 compared to other income of \$286,000 in 2003. This increase in expense was primarily due to the sale of the majority of our synthetic DNA business unit to a group of investors including a former member of management. As a result we recorded a net loss related to the sale of \$9.8 million in the second quarter of 2004.

### *Provision for Income Taxes*

Our effective tax rate decreased to 33% in 2004 from 36% in 2003. Our operating subsidiaries are exposed to effective tax rates ranging from approximately 25% to approximately 42%. Fluctuation in the distribution of pre-tax income among these entities can lead to fluctuations of the effective tax rate in our consolidated financial statements. Further, we received tax benefits in 2004 related to the revaluation of deferred taxes in The Netherlands, the United States, and Norway.

### *Fiscal Year Ended December 31, 2003 compared to 2002*

#### *Net Sales*

In 2003, net sales increased 18% to \$351.4 million from \$298.6 million in 2002. Net sales in the United States decreased to \$154.4 million in 2003 from \$156.0 million in 2002, and net sales outside the United States increased to \$197.0 million in 2003 from \$142.6 million in 2002.

Net sales within the United States decreased primarily as a result of the December 2002 closure of the QIAGEN Genomics facility in Seattle. In 2002, QIAGEN Genomics had reported sales of \$2.5 million. Following the December 2002 closure, we reduced the resources dedicated to genomics services resulting in lower sales. Net sales at QIAGEN, Inc., located in Valencia, California were overall unchanged, but QIAGEN Inc. continued to experience lower prices on the sale of synthetic DNA products due to greater price competition in the synthetic DNA market. We subsequently sold the majority of our synthetic DNA business unit in June 2004. Net sales at GenoVision Inc., which was acquired in the second quarter of 2002 as part of the acquisition of GenoVision A.S. and is located in Pennsylvania, were \$3.2 million in 2003 compared to reported sales of \$1.8 million in the second half of 2002.

Outside of the United States, the increase in net sales was primarily due to strong growth at QIAGEN GmbH, located in Germany, which reported an increase of 41% (\$20.3 million), QIAGEN Inc., located in Canada, which reported an increase of 83% (\$6.1 million), and QIAGEN Ltd., located in England, which reported an increase of 28% (\$5.4 million). Net sales in Japan, which include the results of QIAGEN K.K. and QIAGEN Sciences, K.K. (formerly Sawady) increased 16% (\$5.7 million) in 2003 compared to 2002.



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While unit sales of consumable products increased during the year, we expect a slower rate of sales growth for the range of products designed for large-scale plasmid DNA applications as the market for such products matures. We regularly introduce new products in order to extend the life of our existing product lines as well as to address new market opportunities. During 2003, we released over 60 new products including the LiquiChip Activated Beads which enable efficient covalent immobilization of antibodies and other thiol-containing biomolecules in xMap protein assays. The BioRobot® EZ1, M48 and M96 workstations deliver automation for low- to medium-throughput applications. The BioRobot EZ1 and EZ1 kits provide easy, automated purification of nucleic acids from 1-6 clinical samples for a wide range of sample types. BioRobot M48 and M96 workstations operate with the MagAttract® kits for fully automated nucleic acid purification from 6-48 or 8-96 clinical samples. Other specialized BioRobot systems were introduced for gene expression analysis, genotyping,

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and plant sciences. We launched validated, ready-to-use QuantiTect<sup>®</sup> Gene Expression Assays, for real-time RT-PCR analysis of a constantly expanding range of genes, and QuantiTect Custom Assays, for any target of choice. Our RNeasy<sup>®</sup> product line now includes new kits for difficult-to-lyse samples. The new RNeasy Micro Kit and QIAamp<sup>®</sup> DNA Micro Kit enable purification of RNA and DNA from very small samples. The RNeasy MinElute Cleanup Kit is designed for RNA cleanup and sample concentration. New products for gene silencing in 2003 include 4-for-Silencing siRNA Duplexes for guaranteed, efficient gene silencing. HPP (high performance purity) Grade siRNA enables highly efficient gene silencing. RNAiFect Transfection Reagent and the RNAi Starter Kit facilitate transfection of siRNA into eukaryotic cells. New human and mouse Array-Ready Oligo Sets were launched along with a large number of new animal, bacteria, and plant species, including the first Array-Ready Oligo Sets for the grape genome.

Changes in exchange rates continued to affect the growth rate of net sales for the year ended December 31, 2003. A significant portion of our revenues is denominated in European Union euros. Using identical foreign exchange rates for both years, net sales would have increased approximately 12% as compared to the reported increase of 18% for the year ended December 31, 2003. See [Currency Fluctuations](#).

### *Gross Profit*

Gross profit was \$229.0 million or 65% of net sales in the year ended December 31, 2003 as compared to \$202.1 million or 68% of net sales in 2002. The absolute dollar increase is attributable to the increase in net sales partially offset by the currency impact of the stronger euro. Gross profit was negatively impacted by the currency effect of the stronger euro, since a significant portion of our production is based in Germany, while a significant portion of our sales is in the United States. Gross profit was also negatively impacted by a charge of \$3.6 million in December 2003, as part of our relocation and restructure plan, related to the write-down of inventory which is part of a product line that we will not sell in the future. Additionally, gross profit was negatively impacted by manufacturing costs incurred at our production facilities in Germantown, Maryland and Hilden, Germany, which began production operations in the second quarter of 2002 and fourth quarter of 2002, respectively. These facilities added additional production capacity, which resulted in increased fixed production costs. These higher fixed costs will continue to be a cost of production in the future.

### *Research and Development*

Research and development expenses increased 13% to \$31.8 million (9% of net sales) in 2003 compared with \$28.2 million (9% of net sales) in 2002. Using identical foreign exchange rates for both years, research and development expenses decreased approximately 2%. We expanded our German research facility late in 2002, which resulted in increased costs related to research and development in 2003 compared to 2002. Our U.S. facility located in Germantown, Maryland includes limited research and development activities. As we continue to expand our research activities and product development capabilities, additional research and development expense will be incurred related to facility costs and employees engaged in our research and development efforts. We have a strong commitment to research and development and anticipate that absolute research and development expenses may increase significantly.

### *Sales and Marketing*

Sales and marketing expenses increased 11% to \$83.0 million (24% of net sales) in 2003 from \$75.1 million (25% of net sales) in 2002. Using identical exchange rates for each year, sales and marketing expenses increased approximately 3%. Sales and marketing costs are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses and other promotional items. We anticipate that selling and marketing costs will continue to increase along with new product introductions and continued growth in sales of our products.

*General and Administrative*

General and administrative expenses increased 1% to \$42.3 million (12% of net sales) in 2003 from \$42.0 million (14% of net sales) in 2002. Using identical foreign exchange rates for both years, general and

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administrative expenses decreased approximately 7%. General and administrative expenses primarily represent the costs required to support our administrative infrastructure that continues to expand along with our growth, offset by our recent efforts to lower costs. These efforts include the 2002 closure of our Seattle facility and the implementation of a cost reduction program related to our synthetic DNA business.

### *Relocation and Restructure Costs*

In December 2003, we committed to a relocation and restructure plan. The plan includes the relocation of our North American marketing and sales operations from Valencia, California to Germantown, Maryland in order to utilize the capacity of our North American Headquarters. Additionally, we decided to refocus resources dedicated to certain products related to our microarray business and accordingly discontinued certain products. We expensed approximately \$3.6 million to cost of sales for the write-down of inventories and approximately \$1.5 million to operating expenses related to relocating employees, severance for employees who will not be relocating and the write-off of investments. Additionally, in 2003 approximately \$1.6 million of costs were incurred to complete the closure of the QIAGEN Genomics site in Bothell, Washington, mainly lease related costs.

During December 2002, we decided to close the QIAGEN Genomics site in Bothell, Washington and to relocate several of the site's activities to other locations, mainly to our facilities in Germantown, Maryland and Hilden, Germany. The closure and relocation was completed in the second quarter of 2003 and is expected to contribute to our future profitability as a result of lower operating costs. As a result of the closure and related re-focus of this business, we recorded a charge, in December 2002, of approximately \$10.8 million primarily consisting of: severance and other costs of \$2.7 million, and non-cash write offs of facilities and equipment and other assets of \$4.7 million and of intangible assets, including developed technology and goodwill, of \$3.2 million.

### *Other Income (Expense)*

Other expense was \$1.6 million in 2003 compared to \$4.3 million in 2002. This decrease in expense was mainly due to increased research and development grant income and a net gain on foreign currency transactions in 2003 compared to a net loss in 2002, partially offset by higher interest expense and loss from equity method investees in 2003.

In 2003, research and development grant income from European as well as German state and federal government grants increased to \$2.2 million from \$801,000 in 2002. We conduct significant research and development activities in Germany, and expect to continue to apply for such research and development grants in the future.

We recorded a gain from foreign currency transactions of \$1.1 million in 2003 as compared to a loss of \$2.2 million in 2002. The gain from foreign currency transactions reflects net effects from conducting business in currencies other than the U.S. dollar. QIAGEN N.V.'s functional currency is the U.S. dollar and its subsidiaries' functional currencies are the European Union euro, the British pound, the Swiss franc, the U.S. dollar, the Australian dollar, the Canadian dollar, the Japanese yen and the Norwegian krone. See Currency Fluctuations under Item 11 Quantitative and Qualitative Disclosures About Market Risk.

For the year ended December 31, 2003, interest income increased to \$1.3 million from \$1.2 million in 2002. Interest income is derived from our investment of funds in investment grade, interest-bearing marketable securities and from cash balances. As of December 31, 2003, we had approximately \$6.5 million invested in marketable securities. The weighted average interest rates on the marketable securities portfolio ranged

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from 1.37% to 1.46% in 2003, compared to 1.93% to 2.22% in 2002.

Interest expense increased to \$4.6 million in 2003 compared to \$2.6 million in 2002. Interest costs increased primarily as a result of our additional long-term borrowings related to facility construction.

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In 2003, we recorded net losses from an equity method investee of \$1.8 million compared to \$1.3 million in 2002. The 2003 loss represents our share of losses from our equity investment in PreAnalytiX. The first product of PreAnalytiX, the PAXgene Blood RNA System was launched in April 2001. In August 2002, PreAnalytiX announced that they had been successful in forming agreements with pharmaceutical companies including GlaxoSmithKline for the use of the PreAnalytiX system. In October 2003, PreAnalytiX announced a collaborative effort with Affymetrix, Inc. to improve gene expression results from whole blood RNA samples. We sell certain products directly as joint venture products and certain products are sold via protocols. The joint venture entity itself, PreAnalytiX GmbH, is expected to report net losses for our fiscal year 2004. As previously disclosed, we intend to continue to make strategic investments in complementary businesses as the opportunities arise. Accordingly, we may continue to record losses on equity investments in start-up companies based on our ownership interest in such companies.

### *Provision for Income Taxes*

Our effective tax rate decreased to 36% in 2003 from 41% in 2002. Our operating subsidiaries are exposed to effective tax rates ranging from approximately 8% to approximately 52%. Fluctuation in the distribution of pre-tax income among these entities can lead to fluctuations of the effective tax rate in our consolidated financial statements. Further, we received a tax benefit in 2003 related to the closure of QIAGEN Genomics in 2002.

### *Foreign Currency*

QIAGEN N.V.'s functional currency is the U.S. dollar and its subsidiaries' functional currencies are the local currency of the respective countries in which they are headquartered, in accordance with Statement of Financial Accounting Standard No. 52, "Foreign Currency Translation". All amounts in the financial statements of entities whose functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows: (1) assets and liabilities at period-end rates, (2) income statement accounts at average exchange rates for the period, and (3) components of shareholders' equity at historical rates. Translation gains or losses are recorded in shareholders' equity, and transaction gains and losses are reflected in net income. The net gain or loss on foreign currency transactions was a loss of \$67,000 in 2004, a gain of \$1.1 million in 2003, and a loss of \$2.2 million in 2002, and is included in other income.

### *Liquidity and Capital Resources*

To date, we have funded our business primarily through internally generated funds, debt and the private and public sales of equity. Our primary use of cash has been to support continuing operations and our capital expenditure requirements including acquisitions. As of December 31, 2004 and December 31, 2003, we had cash and cash equivalents of \$196.4 million and \$99.0 million, respectively, and investments in current marketable securities of \$30.2 million and \$6.5 million, respectively. Cash and cash equivalents are primarily held in U.S. dollars, other than those cash balances maintained in the local currency of the subsidiary to meet local working capital needs. At December 31, 2004, cash and cash equivalents had increased by \$97.4 million over December 31, 2003 primarily due to cash provided by operating activities of \$53.8 million and financing activities of \$95.6 million, offset by cash used in investing activities of \$51.1 million. Marketable securities consist of investments in high-grade corporate securities. As of December 31, 2004 and December 31, 2003, we had working capital of \$299.0 million and \$163.6 million, respectively.

***Operating Activities.*** For the years ended December 31, 2004 and 2003, we generated net cash from operating activities of \$53.8 million and \$64.1 million, respectively. Cash provided by operating activities decreased in 2004 compared to 2003 primarily due to increases in deferred taxes and prepaid expenses, partially offset by a loss on the disposition of a significant portion of our synthetic DNA business unit, a decrease in inventories, and increases in accounts payable and accrued liabilities. Since we rely heavily on cash generated from operating activities to fund

our business, a decrease in demand for our products or significant technological advances of competitors would have a negative impact on our liquidity.

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**Investing Activities.** Approximately \$51.1 million of cash was used in investing activities during 2004, compared to \$14.1 million in 2003. Investing activities during 2004 consisted principally of the purchase of intangible assets in connection with our acquisition of MSI, proceeds from the disposition of a portion of our synthetic DNA business unit and the purchases of marketable securities along with the purchases of property and equipment in connection with our operations in the U.S. and Germany. At the end of 2002, we had completed the expansion of our production operation facilities in the U.S. and Germany, and during 2003, had continued to make capital investments related to the new facilities.

**Financing Activities.** Financing activities provided \$95.6 million in cash during 2004, compared to a use of \$1.9 million in 2003. Cash provided during the year was primarily due to the long-term borrowings of the convertible debt proceeds from QIAGEN Finance (Luxembourg) S.A., and the issuance of common shares as a result of stock option exercises, partially offset by the repayment of long-term debt and capital lease payments.

We have credit lines totaling \$12.1 million at variable interest rates none of which was utilized as of December 31, 2004. Additionally, we have capital lease obligations, including interest, in the amount of \$21.9 million. We also carry \$204.2 million of long-term debt that consists of three notes payable.

Two of the notes payable are the long-term borrowings of the proceeds from our issuance of \$150.0 million senior unsubordinated convertible notes, with a 1.5% coupon due in 2024 through QIAGEN Finance (Luxembourg) S.A., which was established for this purpose. According to the provisions of the Financial Accounting Standards Board Interpretation No. 46 (FIN 46) Consolidation of Variable Interest Entities, which is discussed more fully in Note 6 to the Consolidated Financial Statements, QIAGEN Finance is a variable interest entity with no primary beneficiary, thus is not consolidated. Accordingly, the convertible debt is not included in our consolidated financial statements though we do report the full obligation of the debt through our liabilities to QIAGEN Finance. The net proceeds of the convertible debt were loaned by QIAGEN Finance to our consolidated U.S. and Swiss subsidiaries. The long-term notes payable to QIAGEN Finance have an effective rate of 1.95%, and are due in August 2011. The convertible notes issued by QIAGEN Finance are convertible into shares of our common stock at a conversion price of \$12.6449 subject to adjustment. Approximately \$58.0 million of the proceeds was used to repay long-term debt at higher interest rates and approximately \$29.5 million was used to finance the acquisition of MSI. We intend to use the remaining net proceeds for general corporate purposes. The third note is a note payable of EUR 40.0 million, (approximately \$54.2 million at December 31, 2004) which bears interest at a variable interest rate of EURIBOR plus 0.75 percent is due in annual payments of EUR 5.0 million through June 2011.

We believe that funds from operations, existing cash and cash equivalents, together with the proceeds from our public and private sales of equity and convertible notes, and availability of financing facilities as needed, will be sufficient to fund our planned operations and expansion during the coming year.

### ***Currency Hedging***

In the ordinary course of business, we purchase foreign currency exchange options to manage potential losses from foreign currency exposures. The options outstanding at December 31, 2004 expire at various dates through February 2005 and have a fair market value of approximately \$23,000. These options give us the right, but not the requirement, to purchase foreign currencies in exchange for U.S. dollars at predetermined exchange rates. The principal objective of such options is to minimize the risks and/or costs associated with global financial and operating activities. We do not utilize financial instruments for trading or other speculative purposes. Additionally, during 2004, our German and Swiss subsidiaries entered into forward arrangements which qualify for hedge accounting as cash flow hedges of foreign currency denominated liabilities. At December 31, 2004, these forward contracts totaled \$44.0 million as a hedge to currency risk on intercompany loans. The contracts mature in July 2011 and have a fair market value of approximately \$4.8 million, which is included in other liabilities in the accompanying consolidated balance sheet at December 31, 2004.





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As of December 31, 2004, our future contractual cash obligations are as follows:

<u>Contractual obligations (in thousands)</u>	<u>Total</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>Thereafter</u>
Long-term debt	\$ 204,152	\$ 6,769	\$ 6,769	\$ 6,769	\$ 6,769	\$ 6,769	\$ 170,307
Capital lease obligations	21,870	1,971	1,674	1,519	1,519	1,519	13,668
Operating leases	17,471	5,639	3,002	2,097	1,326	1,115	4,292
Purchase obligations	13,408	10,026	935	267	176	176	1,828
<b>Total contractual cash obligations</b>	<b>\$ 256,901</b>	<b>\$ 24,405</b>	<b>\$ 12,380</b>	<b>\$ 10,652</b>	<b>\$ 9,790</b>	<b>\$ 9,579</b>	<b>\$ 190,095</b>

In addition to the above and pursuant to the purchase agreements for the 2004 acquisition of Molecular Staging Inc., we could be required to make additional contingent cash payments totaling up to \$3.0 million based on revenue milestones in 2005.

**Critical Accounting Policies, Judgments and Estimates**

The preparation of our financial statements in accordance with accounting principles generally accepted in the United States requires management to make assumptions that affect the reported amounts of assets, liabilities and disclosure of contingencies as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Critical accounting policies are those that require the most complex or subjective judgments often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Thus, to the extent that actual events differ from management's estimates and assumptions, there could be a material impact to the financial statements. In applying our critical accounting policies, at times we used accounting estimates that either required us to make assumptions about matters that were highly uncertain at the time the estimate was made or it is reasonably likely that changes in the accounting estimate may occur from period to period that would have a material impact on the presentation of our results of operations, financial position or cash flows. Our critical accounting policies are those related to revenue recognition, accounts receivable, investments, goodwill and other intangibles, and income taxes. We reviewed the development, selection, and disclosure of our critical accounting policies and estimates with the Audit Committee of our Supervisory Board.

**Revenue Recognition.** We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements (SAB 104). SAB 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) could require management's judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

**Accounts Receivable.** Our accounts receivable are unsecured, and we are at risk to the extent such amounts become uncollectible. We continually monitor accounts receivable balances, and provide for an allowance for doubtful accounts at the time collection may become questionable based on payment history or age of the receivable. Since a significant portion of our customers are funded through academic or government funding arrangements, past history may not be representative of the future. As a result, we may have write-offs of accounts

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receivable in excess of previously estimated amounts or may in certain periods increase or decrease the allowance based on management's current estimates.

**Investments.** We have equity investments accounted for under the cost method. We periodically review the carrying value of these investments for permanent impairment, considering factors such as the most recent

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stock transactions, book values from the most recent financial statements, and forecasts and expectations of the investee. Estimating the fair value of these non-marketable equity investments in life science companies is inherently subjective, and if actual events differ from management's assumptions, it could require a write-down of the investment that could materially impact our financial position and results of operations.

In addition, generally accepted accounting principles require different methods of accounting for an investment depending on the level of control that we exert. Assessing the level of control involves subjective judgments. If management's assumptions with respect to control differ in future periods and we therefore have to account for these investments under a method other than the cost method, it could have a material impact to our financial statements.

**Goodwill and Other Intangible Assets.** We account for acquisitions under the purchase method of accounting, typically resulting in goodwill. Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets", requires us to assess goodwill for impairment at least annually in the absence of an indicator of possible impairment and immediately upon an indicator of possible impairment. The statement requires estimates of the fair value of our reporting units. If we determine that the fair values are less than the carrying amount of goodwill recorded, we must recognize an impairment in our financial statements. Due to the numerous variables associated with our judgments and assumptions relating to the valuation of the reporting units and the effects of changes in circumstances affecting these valuations, both the precision and reliability of the resulting estimates are subject to uncertainty, and as additional information becomes known, we may change our estimate.

At December 31, 2004, goodwill and intangible assets totaled \$56.3 million and \$34.8 million, respectively, and were included in the following segments:

	<u>Goodwill</u>	<u>Intangibles</u>
Germany	\$ 20,980,000	\$ 19,934,000
United States	5,478,000	2,991,000
Japan	1,405,000	
Norway	28,400,000	3,792,000
Switzerland		1,858,000
The Netherlands		6,183,000
	<u>                    </u>	<u>                    </u>
Total	<u>\$ 56,263,000</u>	<u>\$ 34,758,000</u>

In the fourth quarter 2004, we performed our annual impairment assessment of the goodwill (using data as of October 1, 2004) in our U.S., Japan, Norway and German segments in accordance with the provisions of SFAS No. 142. In testing for potential impairment, we measured the estimated fair value of our reporting units based upon discounted future operating cash flows using a discount rate reflecting our estimated average cost of funds. Differences in assumptions used in projecting future operating cash flows and cost of funds could have a significant impact on the determination of impairment amounts. In estimating future cash flows, we used our internal budgets. Our budgets were based on recent sales data for existing products, planned timing of new product launches or capital projects, and customer commitments related to new and existing products. These budgets also included assumptions of future production volumes and pricing. We concluded that no impairment existed. Even if our estimates of projected future cash flows were too high by 10%, there would be no impact on the reported value of goodwill at December 31, 2004.

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Due to the numerous variables associated with our judgments and assumptions relating to the valuation of the reporting units and the effects of changes in circumstances affecting these valuations, both the precision and reliability of the resulting estimates are subject to uncertainty, and as additional information becomes known, we may change our estimates.

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**Income Taxes.** The calculation of our tax provision is complex due to the international operations and multiple taxing jurisdictions in which we operate. We have significant deferred tax assets due to net operating losses (NOL) the utilization of which is not assured and is dependent on generating sufficient taxable income in the future. Although Management believes it is more likely than not that we will generate sufficient taxable income to utilize all NOL carryforwards, evaluating the NOLs related to our newer subsidiaries requires us to make estimates that we believe are reasonable, but may also be highly uncertain given that we do not have direct experience with such subsidiaries or their products and thus the estimates also may be subject to significant changes from period to period as we gain that experience. To the extent that our estimates of future taxable income are insufficient to utilize all available NOLs, a valuation allowance will be recorded in the provision for income taxes in the period the determination is made, and the deferred tax assets will be reduced by this amount, which could be material. In the event that actual circumstances differ from management's estimates, or to the extent that these estimates are adjusted in the future, any changes to the valuation allowance could materially impact our financial position and results of operations.

The above listing is not intended to be a comprehensive list of all our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles in the United States, with limited or no need for management's judgment. There are also areas in which management's judgment in selecting available alternatives may or may not produce a materially different result. See our audited consolidated financial statements and notes thereto in Item 18 of this Form 20-F which contain a description of accounting policies and other disclosures required by generally accepted accounting principles in the United States.

### ***Authoritative Pronouncements***

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS 123R supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires entities to measure the cost of employee services received in exchange for an award of equity instruments, including grants of employee stock options, based on the grant-date fair value of the award. That cost will be recognized in the income statement over the period during which an employee is required to provide service in exchange for the award (often the vesting period). Pro forma disclosure is no longer an alternative. SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as was permitted under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

We will continue to apply the accounting provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, in accounting for our stock option plan until the effective date of SFAS No. 123R. Please see Note 2 to our consolidated financial statements in this report for the pro forma impact to net income and earnings per share under SFAS No. 123's fair value method of accounting for employee stock plans. SFAS 123R must be adopted no later than January 1, 2006. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123R on January 1, 2006.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 amends ARB No. 43 Chapter 4, *Inventory Pricing* to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is



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permitted for inventory costs incurred during fiscal years beginning after the date this Statement was issued. We will adopt SFAS No. 151 effective January 1, 2005, and we do not expect the adoption to have a material impact on our consolidated financial position or results of operations.

In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46, Consolidation of Variable Interest Entities. This interpretation requires a company to consolidate a variable interest entity if it is designated as the primary beneficiary of that entity even if the company does not have a majority of voting interests. A variable interest entity is generally defined as an entity with insufficient equity to finance its activities or where the owners of the entity lack the risk and rewards of ownership. We adopted this standard in the first quarter of 2004 and it did not have a material impact on our results of operations or financial position of the Company.

**Item 6. Directors, Senior Management and Employees**

Supervisory Directors and Managing Directors are appointed annually for the period beginning on the date following the Annual General Meeting up to and including the date of the Annual General Meeting held in the following fiscal year. The Deputy Managing Director is appointed by the Supervisory Board.

Our Supervisory Directors, Managing Directors and executive officers, and their ages as of February 6, 2005, are as follows:

**Managing Directors and Deputy Managing Director:**

<u>Name</u>	<u>Age</u>	<u>Position</u>
Peer M. Schatz	39	Managing Director, Chief Executive Officer
Roland Sackers	36	Deputy Managing Director, Chief Financial Officer
Dr. Joachim Schorr	44	Managing Director, Senior Vice President, Research and Development
Bernd Uder	47	Managing Director, Senior Vice President, Sales and Marketing

**Supervisory Board Members:**

<u>Name</u>	<u>Age</u>	<u>Position</u>
Prof. Dr. Detlev H. Riesner	63	Chairman of the Supervisory Board, Supervisory Director and Chairman of the Compensation Committee
Dr. Heinrich Hornef	73	Deputy Chairman of the Supervisory Board, Supervisory Director, and Chairman of the Audit Committee
Dr. Metin Colpan	50	Supervisory Director
Jochen Walter	57	Supervisory Director and Member of the Audit Committee
Dr. Franz A. Wirtz	72	Supervisory Director and Member of the Compensation Committee



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Erik Hornnaess	67	Supervisory Director and Member of the Audit Committee
Prof. Dr. Manfred Karobath	64	Supervisory Director

Prof. Dr. jur Carsten P. Claussen was appointed as non-voting Special Advisor to the Supervisory Board and Honorary Chairman in 1999.

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The following is a brief summary of the background of each of the Supervisory Directors, Managing Directors, Deputy Managing Director, and the Honorary Chairman. Supervisory Directors and Managing Directors are appointed annually for the period beginning on the day following the Annual General Meeting up to and including the date of the Annual General Meeting held in the following fiscal year.

**Peer M. Schatz** joined the Company in 1993 and has been Chief Executive Officer since January 1, 2004. Between 1993 and 2003 he was Chief Financial Officer and became a Managing Director in 1998. Mr. Schatz was previously a partner in a private management buyout group in Switzerland and worked in finance and systems positions in Sandoz, Ltd. and Computerland AG as well as in finance, operations, management and sales positions in various start-up companies in the computer and software trading industry in Europe and the United States. Mr. Schatz graduated from the University of St. Gall, Switzerland, with a Master's degree in Finance in 1989 and obtained an M.B.A. in Finance from the University of Chicago Graduate School of Business in 1991. Mr. Schatz also serves in the capacities of Vice Chairman, Audit Committee Chairman and Compensation Committee member to Evotec OAI AG and as director to Mulligan BioCapital AG and acted as a member of the Advisory Board (Börsenrat) of the Frankfurt Stock Exchange through 2004 and also serves as a member of the German Corporate Governance Commission.

**Roland Sackers** joined the Company in 1999 and has been Chief Financial Officer and Deputy Managing Director since January 1, 2004. Between 1999 and 2003 he was Vice President Finance of the Company. Between 1995 and 1999 Mr. Sackers acted as an auditor with Arthur Andersen Wirtschaftsprüfungsgesellschaft Steuerberatungsgesellschaft. Mr. Sackers graduated from the Westfälische Wilhelms-Universität Münster, Germany with an M.B.A. Mr. Sackers has been a member of the Supervisory Board of IBS AG since 2002, a member of the Audit Committee of IBS AG since 2003, and a member of the Board of Directors of Operon Biotechnologies, Inc. since 2004.

**Dr. Joachim Schorr** joined the Company in 1992 and has been Senior Vice President Research & Development since January 1, 2004. He has also been nominated as a Managing Director. Initially, Dr. Schorr served the Company as Project Manager and later had responsibilities as Business Unit Manager. In 1999 Dr. Schorr became Vice President Research & Development with the responsibility for the world-wide QIAGEN R&D activities. Before joining QIAGEN Dr. Schorr worked for the pharmaceutical company Hoechst AG on the development of oral malaria vaccines and was awarded with the IHK research award in 1991. Dr. Schorr holds a Ph.D. in Molecular Biology and Virology, which he received at the University of Cologne. Dr. Schorr is a co-founder of Coley Pharmaceuticals, EnPharma Pharmaceuticals and QBM Cell Sciences.

**Bernd Uder** joined QIAGEN in 2001 as Vice President Sales & Marketing and has been Senior Vice President Sales & Marketing since January 1, 2004. He has also been nominated as a Managing Director. Between 1987 and 2001, Mr. Uder was active in building up and coordinating world-wide distribution networks as Vice President European Biolab Sales & Marketing with Pharmacia and Vice President global e.business with Amersham Pharmacia Biotech.

**Professor Dr. Detlev H. Riesner** is a co-founder of QIAGEN. He has been on the Company's Supervisory Board since 1984 and was appointed Chairman of the Supervisory Board in 1999. Professor Riesner has held the Chair of Biophysics at the Heinrich-Heine-University in Düsseldorf since 1980. In 1996, he was also appointed to the position of Vice President of Research, and in 1999, he was nominated Director of Technology at the University of Düsseldorf. Prior to that he was Professor of Biophysical Chemistry at the Darmstadt Institute of Technology and, from 1975 to 1977, Lecturer of Biophysical Chemistry at Hannover Medical School. He has held guest professorships at the Institute of Microbiology, Academia Sinica, Beijing, and the Department of Neurology at the University of California, San Francisco. He received his M.S. in Physics from Hannover Institute of Technology and his Ph.D. from the University of Braunschweig, with post-graduate work at Princeton University. Professor Riesner is also either a member of the supervisory board or a director of New Lab Bioquality AG, Erkrath; AC Immune S.A., Lausanne and Neuraxo GmbH, Düsseldorf.

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**Dr. Heinrich Hornef** has been on the Company's Supervisory Board since 2000 and was appointed Deputy Chairman of the Supervisory Board and Audit Committee Chairman in 2001. He also serves as a deputy chairman on the board of Heidelberg Innovation GmbH, a biotechnology and life-science venture capital company in Heidelberg, Germany and as chairman of the advisory board of m-phasys GmbH, Tuebingen. He was a member of the supervisory board of the pharmaceutical company Merck KGaA, in Darmstadt, Germany until March 2004, as well as a member of the partners' counsel of E. Merck, in Darmstadt, Germany until June 2004. Prior to his retirement in December 1996, Dr. Hornef served as CFO of Boehringer Mannheim GmbH (1973-1991), as CFO of the Berlin-based Treuhandanstalt, the privatization agency in East-Germany (1992-1994), and as president of its successor organization, BvS (1995-1996).

**Dr. Metin Colpan** is a co-founder of the Company and was Chief Executive Officer and a Managing Director from 1985 through 2003. Dr. Colpan obtained his Ph.D. and M.Sc. in Organic Chemistry and Chemical Engineering from the Darmstadt Institute of Technology in 1983. Prior to founding QIAGEN, Dr. Colpan was an Assistant Investigator at the Institute for Biophysics at the University of Düsseldorf. Dr. Colpan has had wide experience in separation techniques and in the separation and purification of nucleic acids in particular, and has filed many patents in the field. Dr. Colpan currently serves as a supervisory board member of GPC Biotech AG, Ingenium Pharmaceuticals AG and Morphosys AG, each in Munich, Germany and Omnitron AG, in Darmstadt, Germany.

**Jochen Walter** joined the Supervisory Board of QIAGEN in 1988 and has served on the Audit Committee since 1996. Since 1985, Mr. Walter has been the Managing Director of RBS GmbH (previously called Innovatives Düsseldorf), a venture capital company, which was the management company for S-Kapitalbeteiligungsgesellschaft Düsseldorf, mbH. Since 1968, he has been involved in a wide range of management positions in commercial banking. Mr. Walter holds a diploma in banking management from the Banking Institute in Bonn. Mr. Walter currently serves in the capacities of supervisory board member of RBB Management AG and managing director of UCV Unternehmensberatung- und Beteiligungsgesellschaft mbH, Meerbusch, Germany. He has also served in the capacities of supervisory board member of Rhein Biotech N.V., TRAPO AG, and NETEC AG; advisory board member of RBB Regionale Beteiligungs- u. Beratungsgesellschaft der Sparkassen, der Oberlausitz/Niederschlesien u. der Saechsischen Schweiz mbH; management board member of BVK Bundesverband Deutscher Kapitalbeteiligungsgesellschaften-German Venture Capital Association e.V.; and managing director and general manager of S-Kapitalbeteiligungsgesellschaft Düsseldorf, mbH.

**Dr. Franz A. Wirtz** has been a member of QIAGEN's Supervisory Board since 1989. Dr. Wirtz was Managing Director of Grünenthal GmbH, Aachen/Germany, a large, private pharmaceutical company from 1962-1997 and a member of its Advisory Board from 1998-2001. He is Vice Chairman of Paion AG, Aachen and Vice Chairman of Dasgip AG, Jülich, two young German biotech companies. For 10 years Dr. Wirtz was treasurer of the German pharmaceutical industry association. Dr. Wirtz holds a doctorate degree in chemistry from the Rheinisch-Westfälische Technische Hochschule in Aachen whose honorary citizen he became in 2001.

**Erik Hornnaess** has been a member of the Supervisory Board since 1998 and joined the Audit Committee in 2002. Mr. Hornnaess worked for Astra Pharmaceuticals, Sweden from 1965 until 1979 in various management positions in Sweden, Australia, and Canada and, for the last three years of this period, as the General Manager for the Benelux region (Belgium, The Netherlands and Luxembourg). In 1979, he joined Abbott Laboratories European Headquarters in Paris, France and from 1982 he was the Area Vice-President of Abbott Diagnostic Division in Europe, Middle-East and Africa, with headquarters in Wiesbaden, Germany. Mr. Hornnaess retired from Abbott Laboratories on March 1, 1997 and currently serves as non-executive Director of AXIS-SHIELDS Group, Scotland, and MEDISTIM A/S, Norway. Additionally, Mr. Hornnaess served as the Vice-President of European Diagnostic Manufacturers Association (EDMA), Brussels in the period 1995 through 1997. Mr. Hornnaess graduated from Aarhus Handelshøjskole, Denmark with an M.B.A. and obtained a PMD from the Harvard Business School.

**Professor Dr. Manfred Karobath** studied medicine and worked from 1967 to 1980; first, in the Dept. of Biochemistry of the University of Vienna and, after a stage as postdoctoral fellow, he joined the Dept. of



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Psychiatry where he became professor of biological Psychiatry. In 1980, he joined Sandoz Pharma in Basel, first, in drug discovery, and later, he became Senior Vice President and head of R&D, Switzerland. In 1992, Prof. Dr. Karobath joined Rhone Poulenc Rorer ( RPR ) as President of R&D and Executive Vice President and later he became a member of the Boards of Directors of RPR, Pasteur Mérieux Connought, Centeon and Rhone Poulenc Pharma. He has received several scientific awards and has published 92 scientific papers. Dr. Karobath also serves as a member on the board of directors of Coley Pharmaceutical Group, and as a member on the board of director of IDEA AG.

**Professor Dr. jur. Carsten P. Claussen** was Chairman of the Supervisory Board of the Company from 1988 to June 1999 and was appointed as a Special Advisor and Honorary Chairman in 1999. This position is not required by Dutch law and Professor Claussen is no longer a voting member of the Supervisory Board. For many years he has pursued a career in private banking. Between 1976 and 1987, Professor Claussen was a member of the Executive Board of Norddeutsche Landsbank, Hannover, and Chairman of the Hannover Stock Exchange. Since 1987, he has been a lawyer in Duesseldorf and senior advisor to IKB Deutsche Industriegreditbank, Düsseldorf. At present, he is a partner in the law firm of Hoffmann Liebs and Partner and specializes in corporate law and capital market transactions. He is Chairman of the Board of TON ART AG, Duesseldorf; Flossbach & v. Storch Vermögensmanagement AG, Cologne; and WAS Worldwide Analytical Systems AG, Cleve and is a member of other boards. Professor Claussen received his Ph.D. in law from the University of Cologne.

**Compensation of Directors and Officers**

The table below states amounts earned on an accrual basis by Directors and Officers in 2004. The variable component is based on performance relative to personal goals and corporate goals agreed by the Supervisory Board.

The compensation granted to Supervisory Board directors in 2004 consists of fixed compensation for Board members, an additional amount for Chairman and Vice Chairman, and committee membership fees for audit committee members. Board members also receive a variable component, in the form of Stock Options (see below). We did not pay any agency or advisory service fees to members of the Supervisory Board other than to Dr. Colpan for his scientific consulting services. Stock options granted to the Managing and Supervisory Boards must have an exercise price that is higher than the market price at the time of grant.

Year Ended December 31, 2004	Annual Compensation		Long-Term Compensation		
	Fixed Salary	Variable Cash Bonus (1)	Defined Contribution Benefit Plan	Stock Options	Other (2)
Peer M. Schatz	\$ 865,000	\$ 127,000		117,726(3)	\$ 1,000
Roland Sackers	\$ 267,000		\$ 8,000	53,742(3)	\$ 3,000
Dr. Joachim Schorr	\$ 232,000	\$ 90,000	\$ 8,000	12,664(3)	\$ 41,000
Bernd Uder	\$ 247,000	\$ 12,000	\$ 8,000	30,385(3)	\$ 8,000
Supervisory Board:					
Prof. Dr. Detlev H. Riesner	\$ 24,000			20,000(4)	
Dr. Heinrich Hornef	\$ 21,000			20,000(4)	
Dr. Metin Colpan	\$ 12,000			20,000(4)	\$ 509,000(5)
Jochen Walter	\$ 15,000			20,000(4)	
Dr. Franz A. Wirtz	\$ 12,000			20,000(4)	
Erik Hornnaess	\$ 15,000			20,000(4)	
Prof. Dr. Manfred Karobath	\$ 12,000			20,000(4)	

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- (1) Includes one-time payments.
  - (2) Amounts include, among others, inventor bonus and life insurance. Does not include the reimbursement of certain expenses relating to travel incurred at the request of the Company.

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- (3) Options granted at exercise prices ranging from \$8.940 to \$10.047, expiring in July and August 2014.
- (4) Options granted at an exercise price of \$13.913, expiring in April 2014.
- (5) Fee for scientific consulting services.

The following table sets forth the vested and unvested options of our officers and directors as of February 6, 2005:

Name	Total Vested	Total Unvested	Expiration Dates	Exercise Prices
	Options	Options (1)		
Peer M. Schatz	1,149,099	1,100,777	5/2006 to 8/2014	\$ 1.188 to \$20.563
Roland Sackers	257,630	78,778	9/2009 to 8/2014	\$ 4.590 to \$20.563
Dr. Joachim Schorr	86,147	126,033	10/2011 to 8/2014	\$ 5.190 to \$17.90
Bernd Uder	68,555	77,996	3/2011 to 8/2014	\$ 4.590 to \$20.563
Prof. Dr. Detlev H. Riesner	93,999	40,001	5/2006 to 4/2014	\$ 1.188 to \$20.563
Dr. Heinrich Hornef	35,999	40,001	1/2010 to 4/2014	\$ 6.018 to \$20.563
Dr. Metin Colpan	1,030,150	320,000	5/2006 to 4/2014	\$ 1.188 to \$20.563
Jochen Walter	29,333	40,001	1/2010 to 4/2014	\$ 6.018 to \$20.563
Dr. Franz A. Wirtz	73,999	40,001	2/2007 to 4/2014	\$ 3.219 to \$20.563
Erik Hornnaess	65,499	40,001	1/2008 to 4/2014	\$ 5.625 to \$20.563
Prof. Dr. Manfred Karobath	35,999	40,001	1/2010 to 4/2014	\$ 6.018 to \$20.563

- (1) Includes 2004 option grants.

**Audit Committee**

The Audit Committee operates pursuant to a charter approved by the Supervisory Board and consists of three members, Dr. Hornef (Chairman), Mr. Walter, and Mr. Hornnaess, and meets at least quarterly. The Audit Committee members are appointed by the Supervisory Board and serve for a term of one year. We believe that all members of our Audit Committee meet the independence requirements as set forth in the Sarbanes-Oxley Act of 2002 and the Marketplace Rules of the NASDAQ. The Audit Committee recommends and is responsible for the appointment of the independent registered public accounting firm to audit the consolidated financial statements and local books and records of QIAGEN and its subsidiaries, along with pre-approving the fees for such services; reviews the performance of the independent registered public accounting firm with management, discussing on a quarterly basis the scope and results of the reviews and audits with the independent registered public accounting firm; discusses our financial accounting and reporting principles and policies and the adequacy of our internal accounting, financial and operating controls and procedures with the independent registered public accounting firm and management; considers and approves any recommendations regarding changes to our accounting policies and processes; reviews with management and the independent registered public accounting firm our quarterly earnings reports prior to their release to the press; and reviews the quarterly and annual reports (reported on Forms 6-K and 20-F) to be furnished to or filed with the Securities Exchange Commission and the Deutsche Boerse.

**Compensation Committee**

The Compensation Committee consists of two members: Professor Riesner (Chairman) and Dr. Wirtz. Members are appointed by the Supervisory Board and serve for a term of one year. We believe that all of the members of the Compensation Committee meet the independence requirements set forth in the Marketplace Rules of the NASDAQ. The Compensation Committee reviews and approves all stock option grants, reviews and approves the annual salaries, bonuses and other benefits of executive officers, and reviews general policies relating to employee compensation and benefits.

**Employment Contracts**

We have entered into employment contracts with our Managing Directors and our Deputy Managing Director. These contracts are listed as Exhibits under Item 19.



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We have not entered into contracts with any member of the Supervisory Board that provide for benefits upon a termination of the service of the member. We entered into a consulting agreement with Dr. Colpan pursuant to which Dr. Colpan is paid a fee of EUR 2,750 per day (approximately \$3,700 at the December 31, 2004 exchange rate) for consulting services.

**Employees**

As of December 31, 2004, we employed 1,322 individuals, 21% of whom worked in research and development, 32% in sales, 25% in production/logistics, 7% in marketing and 15% in administration.

<b>Country</b>	<b>Research and Development</b>	<b>Sales</b>	<b>Production</b>	<b>Marketing</b>	<b>Administration</b>	<b>Total</b>
United States	11	161	74	34	53	<b>333</b>
Germany	229	106	213	49	98	<b>695</b>
Switzerland	26	18	39	2	13	<b>98</b>
Canada	0	16	0	0	2	<b>18</b>
United Kingdom	0	36	0	5	5	<b>46</b>
France	0	29	0	1	5	<b>35</b>
Australia	0	15	0	0	3	<b>18</b>
Italy	0	8	0	1	3	<b>12</b>
Japan	0	28	0	5	4	<b>37</b>
Norway	10	2	0	0	1	<b>13</b>
Austria	0	4	0	1	2	<b>7</b>
The Netherlands	0	6	0	0	4	<b>10</b>
<b>12/31/2004</b>	<b>276</b>	<b>429</b>	<b>326</b>	<b>98</b>	<b>193</b>	<b>1322</b>

At December 31, 2003 and 2002, we employed 1,533 and 1,651 individuals, respectively. The decrease in the number of employees to 1,322 at December 31, 2004 is primarily due to the 2004 sale of a majority of our synthetic DNA business unit. None of our employees is represented by a labor union or is subject to a collective bargaining agreement. Management believes that its relations with its employees are good.

Our success depends, to a significant extent, on key members of our management and our scientific staff. The loss of such employees could have a material adverse effect on QIAGEN. Our ability to recruit and retain qualified skilled personnel to perform future research and development work 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 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 acquire such personnel or develop such expertise could have a material adverse impact on our operations.

**Table of Contents****Share Ownership**

The following table sets forth certain information as of February 6, 2005 concerning the ownership of Common Shares by our Directors and Officers. In preparing the following table, we have relied on information furnished by such persons.

<u>Name and Country of Residence</u>	<u>Shares Beneficially Owned (1) Number</u>	<u>Percent Ownership (2)</u>
Peer M. Schatz, Germany	1,482,064(3)	1.01%
Roland Sackers, Germany	0(4)	*
Dr. Joachim Schorr, Germany	0(5)	*
Bernd Uder, Germany	0(6)	*
Prof. Dr. Detlev H. Riesner, Germany	2,677,436(7)	1.82%
Dr. Heinrich Hornef, Germany	1,600(8)	*
Dr. Metin Colpan, Germany	6,454,025(9)	4.39%
Jochen Walter, Germany	40,000(10)	*
Dr. Franz A. Wirtz, Germany	1,000,000(11)	*
Erik Hornnaess, Spain	10,000(12)	*
Professor Dr. Manfred Karobath, UK	0(13)	*

\* Indicates that the person beneficially owns less than 1% of the Common Shares issued and outstanding as of February 6, 2005.

- (1) The number of Common Shares issued and outstanding as of February 6, 2005 was 147,028,657. The persons and entities named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them and have the same voting rights with respect to Common Shares.
- (2) Does not include Common Shares subject to options held by such persons at February 6, 2005 and exercisable within 60-days thereafter. See footnotes below for such information on options exercisable at February 6, 2005 and within 60-days thereafter.
- (3) Does not include 1,349,099 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$1.188 to \$20.563 per share. Options expire in increments during the period between May 2006 and August 2014.
- (4) Does not include 267,630 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$4.590 to \$20.563 per share. 33,334 of these options have sales restrictions. Options expire in increments during the period between September 2009 and August 2014.
- (5) Does not include 86,147 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$5.190 to \$17.900 per share. Options expire in increments during the period between October 2011 and August 2014.
- (6) Does not include 39,925 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$4.590 to \$20.563 per share. Options expire in increments during the period between March 2011 and August 2014.
- (7) Does not include 113,999 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$1.188 to \$20.563 per share. Options expire in increments during the period between May 2006 and April 2014. Prof. Riesner also has the option to purchase 162,302 common shares through Credit Suisse First Boston. Includes 2,677,436 shares held by Riesner Verwaltungs GmbH, of which Professor Riesner is the sole stockholder.
- (8) Does not include 55,999 shares issuable upon the exercise of options to purchase Common Shares at an exercise price from \$6.018 to \$20.563 per share. Options expire in increments during the period between January 2010 and April 2014.
- (9) Does not include 1,236,816 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$1.188 to \$20.563 per share. Options expire in increments during the period between May 2006 and April 2014. Includes 5,200,000 shares held by CC Verwaltungs GmbH, of which Dr. Colpan is the sole stockholder and 800,000 shares held by Colpan GbR. Dr. Colpan also has the option to purchase 612,397 common shares through Credit Suisse First Boston.

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- (10) Does not include 49,333 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$6.018 to \$20.563 per share. Options expire in increments during the period between January 2010 and April 2014.
- (11) Does not include 93,999 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$3.219 to \$20.563 per share. Options expire in increments during the period between February 2007 and April 2014.
- (12) Does not include 85,499 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$5.625 to \$20.563 per share. Options expire in increments during the period between January 2008 and April 2014.
- (13) Does not include 55,999 shares issuable upon the exercise of options to purchase Common Shares at an exercise price ranging from \$6.018 to \$20.563 per share. Options expire in increments during the period between January 2010 and April 2014.

*Stock Option Plan*

In April 1996, the Supervisory Board adopted the QIAGEN N.V. 1996 Employee, Director and Consultant Stock Option Plan (the Option Plan), which was approved by our shareholders on June 3, 1996. Pursuant to the Option Plan, options to purchase our Common Shares may be granted to employees and consultants of QIAGEN and its subsidiaries and to Supervisory Directors. An aggregate of 23,968,000 Common Shares have been reserved for issuance pursuant to the Option Plan, subject to certain antidilution adjustments. Options granted pursuant to the Option Plan may either be incentive stock options within the meaning of Section 422 of the United States Internal Revenue Code of 1986, as amended (the Code), or non-qualified stock options. The Option Plan is administered by the Compensation Committee of the Supervisory Board, which selects participants from among eligible employees, consultants and directors and determines the number of shares subject to the option, the length of time the option will remain outstanding, the manner and time of the option's exercise, the exercise price per share subject to the option and other terms and conditions of the option consistent with the Option Plan. The Compensation Committee's decisions are subject to the approval of the Supervisory Board. The vesting and exercisability of certain options will be accelerated in the event of a Change of Control. A Change of Control means the occurrence of a merger or consolidation of QIAGEN, whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of QIAGEN outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) at least 50% of the total voting power represented by the voting securities of QIAGEN or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation, or the stockholders of QIAGEN approve an agreement for the sale or disposition by QIAGEN of all or substantially all of QIAGEN's assets.

The Compensation Committee has the power, subject to Supervisory Board approval, to interpret the Option Plan and to adopt such rules and regulations (including the adoption of sub plans applicable to participants in specified jurisdictions) as it may deem necessary or appropriate. The Compensation Committee or the Supervisory Board may at any time amend the Option Plan in any respect, subject to Supervisory Board approval, and except that (i) no amendment that would adversely affect the rights of any participant under any option previously granted may be made without such participant's consent and (ii) no amendment shall be effective prior to shareholder approval to the extent such approval is required to ensure favorable tax treatment for incentive stock options or to ensure compliance with Rule 16b-3 under the United States Securities Exchange Act of 1934, as amended (the Exchange Act) at such times as any participants are subject to Section 16 of the Exchange Act.

The following table sets forth the total amount of options to purchase Common Shares outstanding under the Option Plan, the range of expiration dates of such options and the prices (in U.S. dollars) at which such options may be exercised, as of February 6, 2005. The exercise price of each of these options is the fair market value of the Common Shares as of the date of grant or at a premium above fair market value.

	<b>Outstanding Options</b>	<b>Expiration Dates</b>	<b>Exercise Price of Shares</b>
1996 Option Plan	12,981,622	5/2006 to 12/2014	\$ 1.060 to \$49.75

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During the fourth quarter of 2004 and considering the new accounting implications of SFAS No. 123R, our Supervisory Board approved the acceleration of the vesting of all unvested stock options with a price greater than \$10.62 previously awarded to employees and officers. The accelerated options were given a sales restriction, such that any shares held through the exercise of an accelerated option could not be sold, prior to the original vesting date. Options held by our Supervisory Board and Managing Directors were not subject to the acceleration. Our Supervisory Board took the action based on its belief that it is in the best interest of our shareholders and the Company as it will reduce our reported compensation expense in future periods. The impact of this acceleration will be to reduce future compensation expense by approximately \$1.4 million after-tax. We are currently working with equity based compensation plan experts to evaluate our stock-based compensation plans and incentive strategies along with the provisions of SFAS No. 123R. Our aim is to implement an equity based compensation plan structure that will give our employees a long-term incentive arrangement, while minimizing our compensation expense.

Options granted to members of the Supervisory Board and the Managing Board must have an exercise price that is higher than the market price at the time of grant. Generally, each of the options has a term of ten years, subject to earlier termination in the event of death, disability or other termination of employment. The outstanding options granted prior to October 2004 become exercisable in cumulative annual installments of 33 1/3 percent each, beginning on the first anniversary date of the grant. The vesting and exercisability of certain of these options will be accelerated in the event of a Change of Control, as discussed above. As of February 6, 2005, options to purchase 4,870,000 Common Shares were held by the officers and directors of QIAGEN, as a group.

### **Exemptions from Certain NASDAQ Corporate Governance Rules**

Exemptions from the NASDAQ corporate governance standards are available to foreign private issuers such as QIAGEN when those standards are contrary to a law, rule or regulation of any public authority exercising jurisdiction over such issuer or contrary to generally accepted business practices in the issuer's country of domicile. In connection with QIAGEN's initial public offering, NASDAQ granted QIAGEN exemptions from certain corporate governance standards that are contrary to the laws, rules, regulations or generally accepted business practices of The Netherlands. These exemptions and the practices followed by QIAGEN are described below:

QIAGEN is exempt from NASDAQ's quorum requirements applicable to meetings of ordinary shareholders. In keeping with the law of The Netherlands and generally accepted business practices in The Netherlands, QIAGEN's Articles of Association provide that there are no quorum requirements generally applicable to meetings of shareholders.

QIAGEN is exempt from NASDAQ's requirements regarding the solicitation of proxies and provision of proxy statements for meetings of shareholders. QIAGEN does furnish proxy statements and solicit proxies for meetings of shareholders. However, the laws of The Netherlands do not provide for a record date to be fixed in advance of a meeting of shareholders. As a result, the holder of the shares on the day of the meeting may vote the shares at the meeting. QIAGEN's transfer agent has implemented procedures to check votes by proxy for validity on the day of the meeting.

QIAGEN is exempt from NASDAQ's requirements that shareholder approval be obtained prior to the establishment of, or material amendments to, stock option or purchase plans and other equity compensation arrangements pursuant to which options or stock may be acquired by directors, officers, employees or consultants. QIAGEN is also exempt from NASDAQ's requirements that shareholder approval be obtained prior to certain issuances of stock resulting in a change of control, occurring in connection with acquisitions of stock or assets of another company or issued at a price less than the greater of book or market value other than in a public offering. QIAGEN's Articles of Association do not require stockholder approval prior to the establishment of a stock option plan. The Articles of Association also permit shareholders to grant the Supervisory Board general authority to issue shares without further shareholder approval. QIAGEN's stockholders have granted the Supervisory Board general authority to issue up to a maximum of the authorized capital of the Company without further

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shareholder approval. QIAGEN plans to seek shareholder approval of stock plans and stock issuances only where required under the law of The Netherlands or under QIAGEN's Articles of Association.

**Item 7. Major Shareholders and Related Party Transactions**

The following table sets forth certain information as of December 31, 2004, concerning the ownership of Common Shares of each holder of greater than five percent ownership. None of these holders have any different voting rights than other holders of our Common Shares.

<u>Name and Country of Residence</u>	<u>Shares Beneficially Owned (1)</u>	
	<u>Number</u>	<u>Percent Ownership</u>
FMR Corp. United States	22,022,710(2)	14.97%

- (1) The number of Common Shares issued and outstanding as of December 31, 2004 was 147,020,207
- (2) Of the 22,022,710 shares attributed to FMR Corp., it has sole voting power over 5,635,011 shares and sole dispositive power of all 22,022,710 shares. Such voting and dispositive power is also attributable to Edward C. Johnson III and Abigail P. Johnson by virtue of their positions, Chairman and Director, respectively, and ownership interests in FMR Corp. This information is based solely on the Schedule 13G filed jointly by FMR Corp., Edward C. Johnson III, Abigail P. Johnson and Fidelity Management and Research Company with the Securities and Exchange Commission on February 14, 2005, which reported ownership as of December 31, 2004. At December 31, 2003, FMR Corp. beneficially owned 8,003,182 shares representing 5.47% if the total Common Shares issued and outstanding at that time.

Our common stock is traded on the NASDAQ National Market in the United States, and on the Prime Standard Segment of the Frankfurt Stock Exchange in Germany. A significant portion of our shares are held in street name, therefore we generally have no way of determining who our shareholders are, their geographical location or how many shares a particular shareholder owns. Based on the information available to us, we estimate that institutional and retail investors in the United States hold approximately 30% to 40% of our common shares.

*Control of Registrant*

To our knowledge, we are not directly or indirectly owned or controlled by another corporation, by any foreign government, or by any other natural or legal person. As of February 6, 2005, the officers and directors of QIAGEN as a group beneficially owned 11,665,125 Common Shares or 7.93% of the then outstanding Common Shares.

*Related Party Transactions*

From time to time, we have transactions with companies in which we hold an interest all of which are individually and in sum immaterial except for certain transactions with the joint venture PreAnalytiX, Operon Biotechnologies, Inc. and QIAGEN Finance.

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We have a 50% interest in a joint venture company, PreAnalytiX GmbH, which is accounted for under the equity method. To date, both joint venture partners have loaned equal amounts to the venture at a 4.0% interest rate. It is anticipated that both joint venture partners will convert the loan balances to additional capital at some future date. Amounts due to/from PreAnalytiX at year end are summarized as follows:

	As of December 31,	
	2004	2003
Loan receivable	\$ 5,192,000	\$ 4,524,000
Accounts receivable	\$ 5,869,000	\$ 828,000
Accounts payable	\$ 114,000	\$ 287,000

In 2004, we sold a significant portion of our synthetic DNA business unit to Operon Biotechnologies, Inc. (OBI) and agreed to provide certain transition services for a period of six months. We currently have a 16%

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ownership interest in OBI and hold one board seat. We also have a Manufacturing and Supply Agreement with OBI, wherein we granted to OBI an exclusive license to manufacture and supply certain RNA products to us. During the year, we also sold to OBI certain technology and licenses for \$5.9 million. As of December 31, 2004, we had a loan receivable from OBI of \$7.7 million, accounts receivable from OBI of \$905,000 and accounts payable to OBI of \$510,000.

We have a 100% interest in QIAGEN Finance (Luxembourg) S.A. (QIAGEN Finance), a company established for the purpose of issuing our convertible debt. As discussed in Note 6, QIAGEN Finance is a variable interest entity with no primary beneficiary, thus is not consolidated. Accordingly, the convertible debt is not included our consolidated financial statements, though we do report the full obligation of the debt through our liabilities to QIAGEN Finance. As of December 31, 2004, we had a loan payable to QIAGEN Finance of \$150.0 million, accrued interest due to QIAGEN Finance of \$3.5 million, and accounts receivable from QIAGEN Finance of \$2.5 million.

In 2004 we entered into a consulting agreement with Dr. Metin Colpan, our former Chief Executive Officer and current Supervisory Board member, pursuant to which Dr. Colpan is paid a fee of EUR 2,750 per day for consulting services. During 2004 we paid approximately \$509,000 to Dr. Colpan for scientific consulting services under this agreement.

## **Item 8. Financial Information**

See Item 18.

## **Legal Proceedings**

We are not a party to any material litigation in any court, and management is not aware of any contemplated proceeding by any individual, company or government authority against us.

## **Statement of Dividend Policy**

We have not paid any dividends on our Common Shares since our inception and do not intend to pay any dividends on our Common Shares in the foreseeable future. We intend to retain our earnings, if any, for the development of our business.

## **Item 9. The Listing of QIAGEN's Common Shares**

Our shareholders approved a four-for-one stock split during fiscal 2000.

To effect the four-for-one stock split, on June 16, 2000, our shareholders approved the amendment of our Articles of Association to increase the number of authorized shares of common stock from 65 million to 260 million. Our Board of Supervisory Directors and Managing Board

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approved the split in May 2000. Common shareholders of record on July 3, 2000 received three additional shares for each share held on that date. The additional shares were distributed and the stock split was effective on July 13, 2000.

Effective February 15, 2005, our common shares began being quoted on the NASDAQ National Market under the symbol QGEN. Previously, since June 27, 1996, our common shares had been quoted on the NASDAQ National Market under the symbol QGENF. The following table sets forth the annual high and low closing sale prices for the last five years, the quarterly high and low closing sale prices for the last two fiscal years, and the monthly high and low closing sale prices for the last six months of our common shares on the NASDAQ National Market. All share prices prior to July 13, 2000 have been restated to reflect the stock split.

	<b>High (\$)</b>	<b>Low (\$)</b>
Annual		
2000	57.375	18.813
2001	35.375	12.380
2002	20.810	4.510
2003	12.850	5.200
2004	15.610	8.740



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	<b>High (\$)</b>	<b>Low (\$)</b>
	<hr/>	<hr/>
Quarterly 2003:		
First Quarter	6.200	5.340
Second Quarter	10.090	5.200
Third Quarter	12.850	8.480
Fourth Quarter	12.250	10.330
	<b>High (\$)</b>	<b>Low (\$)</b>
	<hr/>	<hr/>
Quarterly 2004:		
First Quarter	15.610	12.210
Second Quarter	13.640	10.880
Third Quarter		