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QIAGEN NV  
Form 20-F  
April 02, 2002

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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, 2001

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  
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)

Securities registered or to be registered pursuant to Section 12(b) of the Act:  
None

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

Title of class:  
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Common Shares, par value EUR .01 per share

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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, 2001 was 143,463,800.

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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 97.

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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The Company's name together with its logo is registered as a trademark in The Netherlands, the United States and a number of other countries: QIAGEN(R). Other trademarks registered in the United States - inter alia: QIAexpress(R), QIAwell(R), QIAEX(R), QIAprep(R), QIAScreen(R), QIAamp(R), QIAclean(R), QIAquick(R), Oligotex(R), RNeasy(R), BIOROBOT(R), ENDOFREE(R), R.E.A.L.(R), PolyFect(R), SuperFect(R), DNeasy(R), EFFECTENE(R), UltraFect(R), HotStarTaq(R), Catrimox(R), TGGE(R), TurboFilter(R), MagAttract(R), Masscode(R) and ROSYS(R). Registered trademarks in countries outside of the United States include: QIA(TM), DyeEx(TM), HiSpeed(TM), Omniscript(TM), Sensiscript(TM), Targetene(TM), TransMessenger(TM), DirectPrep(TM), InhibitEX(TM), DoubleTag(TM), ImmunEasy(TM), QIABRANE(TM), PECURA(TM), ImmunEasy(TM), QuantiScript(TM), UltraSens(TM), pAlliance(TM), MinElute(TM), ProofTaq(TM) and VARISPAN(TM). Trademarks registered only in Germany: ProofStart(TM) and EverGene(TM). In 2001, five trademark applications were filed in Germany, Countries of the European Community, Japan and the United States of America for RNAProtect(TM), DNAProtect(TM), LiquiChip(TM), CryoCell(TM), and SensiChip(TM).

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 22, 2002, was \$0.8791 per EUR 1.

For information regarding the effects of currency fluctuations on the Company's

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results, see Item 5. "Operating and Financial Review and Prospects".

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PART I

Item 1. Not applicable

Item 2. 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 statement of income data for each of the three fiscal years in the period ended

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December 31, 2001 and the consolidated balance sheet data at December 31, 2001 and 2000 are derived from the Consolidated Financial Statements of the Company which have been audited and reported upon by Arthur Andersen LLP, independent public accountants, and are included herein. The data presented as of and for the fiscal years ended December 31, 1998 and 1997, and the consolidated balance sheet data as of December 31, 1999, 1998 and 1997, is derived from audited consolidated financial statements not included herein.

1. 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 thereon) and "Operating and Financial Review and Prospects."

Consolidated Statement of Income Data:

Year Ended December 31,

	2001	2000	1999	1998
	-----	-----	-----	-----
Net sales	\$ 263,770	\$216,802	\$ 158,155	\$120,8
Cost of sales	79,673	65,436	45,836	38,1
Gross profit	184,097	151,366	112,319	82,6
Operating Expenses:				
Research and development	26,769	23,372	17,813	13,4
Sales and marketing	64,830	54,931	39,948	32,7
General and administrative	36,022	31,177	26,110	20,5
Acquisition costs	3,000	5,353	-	
In-process research and development	-	-	5,100	
Total operating expenses	130,621	114,833	88,971	66,7
Income from operations	53,476	36,533	23,348	15,9
Other income, net	2,847	2,591	1,640	2,8
Income before provision for income taxes and minority interest	56,323	39,124	24,988	18,8
Provision for income taxes	21,896	18,085	10,950	5,4
Minority interest	8	36	149	1
Net income	\$ 34,419	\$ 21,003	\$ 13,889	\$ 13,1
	=====	=====	=====	=====
Basic net income per common share/1/	\$ 0.24	\$ 0.15	\$ 0.10	\$ 0.
	=====	=====	=====	=====
Diluted net income per common share/1/	\$ 0.24	\$ 0.14	\$ 0.10	\$ 0.
	=====	=====	=====	=====
Weighted average number of common shares used to compute basic net income per common share	142,962	142,040	140,317	139,7
Weighted average number of common shares used to compute diluted net income per common share	145,055	145,071	142,186	141,3

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 1 Computed on the basis described for net income per common share in Note 4 of the "Notes to Consolidated Financial Statements".

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Consolidated Balance Sheet Data:

December 31,

	2001	2000	1999	1998
Cash and cash equivalents	\$ 56,460	\$ 24,008	\$ 12,393	\$ 6,5
Working capital	\$ 119,448	\$ 101,527	\$ 57,275	\$ 46,2
Total assets	\$ 356,968	\$ 240,893	\$ 154,331	\$ 110,4
Total long-term liabilities, including current portion	\$ 88,333	\$ 29,320	\$ 17,930	\$ 8,2
Total shareholders' equity	\$ 212,975	\$ 167,356	\$ 96,872	\$ 76,2
Common shares	\$ 1,458	\$ 1,450	\$ 1,435	\$ 2,4
Shares outstanding	143,464	142,548	140,815	139,8

2. Risk Factors

This Annual Report and the documents incorporated herein by reference contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. 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 which could cause actual results to differ materially from those described in the forward-looking statements. 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. 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.

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 \$75.4 million in 1997 to \$263.8 million in 2001. We have recently opened our new research and manufacturing facility in Germantown, Maryland, upgraded our operating and financial systems and expanded the geographic area of our operations, resulting in substantial growth in the number of our employees, as well as increased responsibility for both existing and new management personnel. The rapid expansion of our business and growth in 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, sales and marketing and customer support programs, enhance our operational and financial control systems, expand, train

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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.

We may have difficulty integrating acquisitions of technologies and businesses

During the past several years we have consummated a number of acquisitions 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 to expand our existing and planned business. We may not be able to achieve the benefits expected from any potential acquisition in a reasonable time frame, or at all. 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;

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- . incurrence or assumption of debt; or
- . additional expenses associated with future amortization or impairment of acquired intangible assets or potential businesses.

Our failure to address these risks successfully could have a material adverse effect on our business.

Our operating results may vary significantly

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

Our common shares may have a volatile public trading price

The market price of the common shares since our initial public offering in June 1996 has increased significantly and been highly volatile. In addition to overall stock market fluctuations, factors which may have a significant impact on the market price of the common shares include:

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- . 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;
- . and general market conditions relating to the 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.

Exchange rate fluctuations may adversely affect our business

Since we currently market our products in over 42 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 incurred. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effects of exchange rate fluctuations upon future operating results. While we engage in foreign exchange hedging transactions to manage our foreign currency exposure, there can be no assurance that our hedging strategy will adequately protect our operating results from the effects of future exchange rate fluctuations.

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

The Company's customers within the scientific research markets typically do not keep a significant inventory of QIAGEN products and consequently require overnight delivery of purchases. As such, the Company heavily relies on air cargo carriers such as 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 nucleic acid purification. If there are no adequate delivery alternatives available, sales levels could be negatively affected.

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

Our continued growth is dependent on new product introductions that are well received in the market. We focus our product development efforts on expanding our existing products and developing innovative new products in selected areas where we have expertise and have identified substantial unmet market needs. There can be no assurance that we will be able to introduce new products or that new product releases will be successfully launched and received by our customers.

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Competitors may render some or all of our products or future products noncompetitive

Our primary competition stems from traditional separation and purification 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-based separation and purification technologies and products. There can be no assurance, however, as to how quickly such conversion will occur. We also experience, and expect to continue to experience, increasing competition in various segments of our nucleic acid-based separation business from companies providing nucleic acid-based separation products in kit form. Certain of such competitors have substantially greater financial, research and development, sales and marketing and personnel resources than we do and may have significantly more experience in developing, manufacturing, marketing and supporting new products. There can be no assurance that such companies will not develop products that are directly competitive with our current or planned products or that they will not be able to penetrate markets more rapidly than we can. To the extent that our sales depend on future sales of diagnostic or therapeutic products by our customers, we may also be adversely affected by the intense competition in the pharmaceutical and biotechnology industries. If QIAGEN is not able to maintain its technological advantage over competing products, to expand its market presence, to preserve customer loyalty and thus to compete effectively against its existing or future competitors, QIAGEN's financial condition and results of operations could be materially adversely affected.

Rapid technological change may render some or all of our technologies and products obsolete

Extensive research and technological change characterize our business environment, and new developments are expected to continue at a rapid pace. There can be no assurance that developments by others will not render our technologies and products uneconomical or obsolete.

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 with respect thereto. We currently own 32 issued patents in the United States, 27 issued patents in Germany and 166 issued patents in other major industrialized countries. In addition, we have approximately 235 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 continuing to evolve. 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 owned by or licensed to us 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 owned by or licensed to us will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide competitive advantages to us.

The biotechnology industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We are aware that patents have been applied for and/or issued to third parties claiming technologies for the separation and purification of nucleic acids that are



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closely related to those used by us. 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 and/or products infringe any proprietary rights of third parties. However, there can be no assurance that third parties will not challenge our activities and, if so challenged, that we will prevail. In addition, the patent and proprietary rights of others could require us to alter our products or processes, pay licensing fees or cease certain activities, and there can be no assurance that we will be able to license any technologies that we may require on acceptable terms. In addition, litigation, including proceedings that may be declared by the U.S. Patent and Trademark Office or the International Trade Commission, may be necessary for us 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 to us, and there can be no assurance that we would prevail in any such proceedings.

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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 also can be no assurance that any confidentiality agreements between us and 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 from time to time may 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 rely on collaborative commercial relationships to develop some of our products

Our long-term business strategy includes entering into strategic alliances or 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 be able to negotiate such collaborative arrangements on acceptable terms, or that any such relationships will be scientifically or commercially successful. In addition, there can be no assurance that we will be able to maintain such relationships or that our collaborative partners will not pursue or develop competing products or technologies, either on their own or in collaboration with others.

We have risks relating to doing business internationally

Our business involves operations in several countries. Our current consumable and BioRobot production and manufacturing facilities are located in

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Germany, our instrumentation facility is located in Switzerland, and we have added, through the acquisition of the Sawady group of companies in Tokyo, and establishment of QIAGEN Operon GmbH in Cologne, our synthetic DNA production businesses in Japan and Germany. We expect to begin production of certain of our consumable products at our new facility in Germantown, Maryland in the second quarter of 2002. We also operate U.S. facilities in Alameda, California (synthetic DNA production), Valencia, California (sales and distribution), and Bothell, Washington (single nucleotide polymorphism (SNP) analyses). We also have established sales subsidiaries in Japan, the United Kingdom, France, Switzerland, Australia, Canada and Italy. In addition, our products are sold through independent distributors serving more than 42 other countries.

Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. We have invested heavily in computerized information systems in order to manage more efficiently the widely dispersed components of our operations. In the past year, we have expanded our SAP business information system that integrates 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

Our success depends, to a significant extent, on key members of our management and scientific staff. The loss of such employees could have a material adverse effect on us. 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

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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.

In addition, we have outstanding loan facilities at December 31, 2001 of approximately EUR 70.4 million, which will become due in May 2003. To the extent that our existing resources are insufficient to fund our activities, we may need to raise funds through public or private financings of debt or equity securities. No assurance can be given that such additional financings 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, the issuance of such securities could result in dilution to our shareholders.

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, 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 our customers of diagnostic and pharmaceutical products, which will require pre-clinical studies and clinical trials. 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.

Risk of price controls is a threat to our profitability

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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

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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 biotech industry, the diagnostics industry and the pharmaceutical industry, as a whole, is 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 product liability

The marketing and sale of nucleic acid-based products and services for certain applications entail a potential risk of product liability, and there can be no assurance that product liability claims will not be brought against us. We currently carry product liability insurance coverage, which is limited in scope and amount, but which we believe is currently appropriate for our purposes. There can be no assurance, however, that we will be able to maintain such insurance at reasonable cost and on reasonable terms, or that such insurance will in fact be adequate to protect us against any or all potential claims or losses.

Provisions of our Articles of Association and Dutch law may inhibit a takeover, which could limit the price investors might be willing to pay in the future for our common shares

Our Articles of Association (the "Articles of Association") and the applicable laws of The Netherlands contain provisions that may have anti-takeover effects. Among other things, the Articles of Association provide that our joint meeting of the Supervisory Board and Managing Board (the "Joint Meeting") may make binding nominations for the election of directors, which can only be overridden by shareholders with a two-thirds majority of the votes cast, which majority must represent more than 50 percent of the outstanding shares; that preference shares may in certain instances be issued to third parties selected by us giving such parties preferred dividend rights and placing additional votes in hands friendly to our Supervisory Board; that significant transactions such as a merger or sale of substantially all our assets can only be approved by specified super-majority votes unless such transactions were proposed to the general meeting by the Supervisory Board; and that the Articles of Association can only be amended based on a proposal of our Supervisory Board. Such provisions may have the effect of delaying, deterring or preventing a change in control that might otherwise be considered to be in the best interest of shareholders.

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 the common shares. The lending arrangement entered into by QIAGEN GmbH with Deutsche Bank in 2001, limits the amount of distributions that can be made to QIAGEN N.V. during the period the

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borrowings are outstanding. 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.

We do not anticipate paying dividends on our common shares

We have not paid cash dividends since our inception and do not anticipate paying any cash dividends on the common shares for the foreseeable future. Although we do not anticipate paying any cash dividends, any cash dividends paid in a currency other than the U.S. dollar will be subject to the risk of foreign currency transaction losses.

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, 2001, we had outstanding 143,463,800 common shares plus 8,231,657 outstanding stock options, of which 3,969,284 were exercisable at December 31, 2001. A total of 18,968,000 common shares are reserved for issuance under our stock option plan. All of our outstanding common shares are freely saleable except 12,206,612 shares held by our affiliates, which are subject to certain limitations on resale.

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 the United States. In addition, certain members of our Managing and Supervisory Boards, our officers and certain experts named herein reside outside the United States. As a result, it may be difficult for investors to effect

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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

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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

QIAGEN N.V. (the Company) was incorporated on April 29, 1996 as a public limited liability company ("naamloze vennootschap") under Dutch law as a holding company for its wholly owned subsidiaries, and has its legal seat in Venlo, The Netherlands. The Company's principal executive office is located at Spoorstraat 50, 5911 KJ Venlo, The Netherlands, and its telephone number is +31 77 320 8400. Parties within the United States may also contact QIAGEN, Inc. in Valencia, California at 800-426-8157 to obtain information.

The Company's wholly owned subsidiaries include as of February 15, 2002:

- . QIAGEN GmbH (Germany),
- . QIAGEN Ltd. (England),
- . QIAGEN AG (Switzerland),
- . QIAGEN S.A. (France),
- . QIAGEN Pty. Ltd. (Australia),
- . QIAGEN Inc. (Canada),
- . QIAGEN K.K. (Japan)
- . QIAGEN S.p.A. (Italy),
- . QIAGEN Instruments AG, formerly Rosys Instruments AG (Switzerland),
- . QIAGEN Operon GmbH (Germany),
- . Sawady Technologies Co., Ltd. (Japan), and
- . QIAGEN North American Holdings, Inc. (United States).

QIAGEN North American Holdings, Inc. was established on February 24, 2000, and wholly owns the subsidiaries QIAGEN, Inc. (United States), QIAGEN Sciences, Inc. (United States), QIAGEN Genomics, Inc. (United States), and QIAGEN Operon, Inc. (United States).

Equity investments of the Company include as of February 15, 2002:

- . PreAnalytiX GmbH (50%)
- . QE Diagnostiksysteme GmbH (50%)

As of February 15, 2002, the Company had three facilities under construction. The Company's new research and manufacturing facility, QIAGEN Sciences, Inc., located in Germantown, Maryland, is almost complete and manufacturing activities are anticipated to begin during the second quarter of 2002. This new facility has been primarily financed with intercompany loans and long-term debt. Construction on two new German facilities (a production building and an administrative building) commenced in October 2000, with estimated completion in the third quarter of 2002. The estimated cost for these facilities is approximately EUR 54.0 million (approximately \$48.1 million) and will be

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financed with long-term bank loans. During 2001, the Company obtained new loan facilities allowing the Company to borrow up to a total of EUR 100.0 million (approximately \$89.0 million).

On March 31, 2001, the Company completed the acquisition of the Sawady Group of companies located in Tokyo, Japan in a transaction accounted for as a

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pooling of interests. Under the terms of the agreement QIAGEN N.V. issued 854,987 shares of its common stock, valued at the time of the closing at approximately \$18.0 million, in exchange for all of the outstanding capital stock of Sawady Technology Co., Ltd., Omgen Co., Ltd. and a majority position of 55 percent in Accord Co., Ltd., the three companies comprising the Sawady Group of companies. The Sawady Group of companies was managed and structured as one organization, but was organized as three companies to meet the tax planning and other preferences of its shareholders. In connection with this merger, the Company recorded acquisition and related charges of approximately \$3.0 million, which include approximately \$1.0 million of direct transaction costs (primarily legal and other professional fees) and approximately \$2.0 million of expenses primarily relating to the relocation, closure and elimination of leased facilities, such as duplicate field offices. In October 2001, Omgen Co., Ltd. was merged into Sawady Technology Co., Ltd. The Company believes that the Sawady Group has built a very strong reputation and position as the second largest supplier of synthetic nucleic acids in Japan. The Company intends to leverage QIAGEN Operon, Inc.'s technology-leading position in synthetic nucleic acids with the strong market position that the Sawady Group has created in Japan to address this rapidly expanding market. QIAGEN believes that the worldwide market for synthetic nucleic acid products is growing rapidly.

In January 2001, the Company purchased the 40 percent ownership of QIAGEN K.K. held by the minority shareholder for JPY 4,000,000 (approximately \$35,000).

On June 30, 2000, the Company sold its 50 percent equity ownership in Rosys, Inc.

On June 29, 2000, the Company completed the acquisition of the shares of Operon Technologies, Inc., since renamed QIAGEN Operon, Inc. (Operon), a recognized leader in the area of high-end and added-value synthetic DNA, as well as in the area of tools building on synthetic DNA expertise, such as synthetic genes and DNA microarray tools. Operon is located in Alameda, California. The transaction qualified as a tax-free reorganization and was accounted for as a pooling of interests. Operon shareholders received 2,392,432 shares of QIAGEN common shares (approximately \$104 million at the time of acquisition) for all outstanding shares of Operon stock. Using Operon's leading U.S. technology and market position in high-quality, high-precision, and high-throughput synthetic nucleic acids as well as opportunities for new and powerful joint products, QIAGEN expects significant expansion into the dynamic areas of today's genomics and genetic analysis markets. QIAGEN Operon GmbH in Cologne, Germany commenced operations in 2001 to provide European customers with the same products offered by Operon in the U.S.

On June 1, 2000, the Company established a new sales subsidiary, QIAGEN S.p.A., located in Milan, Italy. In February, 2000, the Company established two new U.S. subsidiaries: QIAGEN North American Holdings, Inc., a company established as a holding company for the U.S. subsidiaries, and QIAGEN Sciences, Inc., the Company's new North American manufacturing and research and development headquarters located in Germantown, Maryland.

### Business Overview

QIAGEN believes, based on the nature of its products and technologies and on its United States and European market shares as supported by independent market studies, that it is the world's leading provider of innovative enabling technologies and products for the separation and purification of nucleic acids. Since 1986, the Company has developed and marketed a broad range of proprietary products for the academic and industrial research market. The increased understanding of nucleic acid structure and function combined with the development of technologies such as Polymerase Chain Reaction (PCR) have resulted in a rapid expansion in the potential uses of nucleic acids beyond the

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research market into developing commercial markets. These include (1) genomics, (2) nucleic acid-based molecular diagnostics, and (3) genetic vaccination and gene therapy. The Company believes that by targeting its enabling nucleic acid separation and purification technologies to numerous participants in each of these developing commercial markets, it will optimize and diversify its opportunities for growth. QIAGEN has experienced significant growth in the past, and since January 1, 1999, has had compounded annual growth through December 31, 2001 of approximately 30% in net sales and 38% in net income, after acquisition charges.

QIAGEN's objective is to expand its leadership position by employing the following strategies: (1) to expand its leadership in the research market and to leverage such leadership to diversify its opportunities for future growth into an array of developing commercial markets, (2) to maintain and further expand technology leadership by investing significant resources in research and development and through strategic acquisitions (3) to provide a comprehensive portfolio of products for specific nucleic acid handling, separation and purification applications, (4) to accelerate consumable sales through new automation product lines, and (5) to emphasize customer contacts and service.

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### 1. Industry Background

Nucleic acids are the fundamental regulatory molecules of life. They take two basic forms, DNA and RNA, that contain and convey the instructions that govern all cellular activities, including protein manufacture and cell reproduction. DNA and RNA consist of linear strands of nucleotide bases, the specific sequences of which constitute the genetic information in the cell. The unique genetic blueprint for all living organisms, from bacteria to human beings, is encoded in the DNA, which is organized into functional units called genes. In order for a cell to read the genetic blueprint, the genetic information encoded in the DNA must first be copied to RNA, which is then used as the template for protein production. Proteins carry out the cellular functions encoded in the RNA copy of the DNA. Any defect or mutation in the sequence of nucleotide bases in the DNA or RNA can disrupt cell or protein function and lead to disease.

Over the past 20 years, developing a better understanding of the fundamental role of nucleic acids in regulating life at the cellular level has been a major focus of basic molecular biology research. In the 1980's, the biotechnology and pharmaceutical industries used the results of this research to develop therapeutic recombinant proteins such as insulin, interferon, and human growth hormone. Major advances continue to be made in the development of technologies to isolate specific nucleic acids, identify their sequences and structures, and determine their functions. Basic molecular biology research is currently conducted in more than 40,000 academic and commercial laboratories worldwide. An example of a major international initiative in this area is the Human Genome Project with an estimated cost of more than \$3 billion. This project, the first phase of which was completed in 2000, involves several hundred academic, governmental, and industrial research laboratories all working to determine the sequence of the approximately 3 billion nucleotide bases which comprise the human genome, in order to identify the functional genes in the human body. Over 400 similar genome sequencing projects are currently underway for many clinically relevant bacteria, fungi, and parasites, as well as plants and animals, with those of the fruit fly *Drosophila melanogaster* and the flowering plant *Arabidopsis thaliana*, both widely used as model organisms, completed in 2000. The increased understanding of nucleic acid structure and function, coupled with the expanding use of innovative technologies such as PCR, has created significant potential for the use of nucleic acids in a broad array



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of therapeutic and diagnostic applications.

These new potential applications have resulted in emerging commercial markets for nucleic acid-based technologies and products, including: (1) DNA sequencing and gene-based drug screening (genomics), (2) nucleic acid-based molecular diagnostics, and (3) genetic vaccination and gene therapy. DNA sequencing determines the specific order of nucleotide bases and is used to identify and understand the regulation and function of genes and their relationship to diseases such as obesity and type II diabetes. This understanding facilitates gene-based drug development, a more targeted development of drugs that may have the ability to affect the regulation and function of the genes themselves. Nucleic acid-based molecular diagnostics represent a new generation of technologies for applications such as genetic "fingerprinting" and the detection of genetic or infectious diseases such as tuberculosis and hepatitis. Targeting the unique nucleic acid sequence of disease-causing agents offers significantly greater specificity and sensitivity than current immunoassay approaches. Commercial development in this area has been advanced by the availability of amplification technologies such as PCR, which exponentially increase the quantity of the target nucleic acid sequence, enhancing detection. Genetic vaccination and gene therapy are applications under development which may eventually lead to the prevention and treatment of diseases by using nucleic acids themselves as vaccines and drugs. In genetic vaccination, diseases such as hepatitis, AIDS, and influenza may be combated using a nucleic acid sequence as the vaccine, instead of using a recombinant protein or an inactivated infectious agent. Medical researchers believe that through gene therapy, diseases such as cancer, diabetes, asthma or coronary artery disease may someday be cured by replacing disease-causing genes with genes containing the correct DNA sequences.

Molecular biology research and its related developing commercial markets all require highly pure nucleic acids. The availability of pure nucleic acids is critical for the reliability and reproducibility of molecular biology experiments in both academic and industrial research laboratories, for the accuracy of results in nucleic acid-based molecular diagnostics, and for the safety of nucleic acid-based vaccines and drugs for human use. Nucleic acids are fragile molecules, which must be rapidly isolated from other cellular components in order to maintain their structural integrity and biological activity, making the separation and purification of nucleic acids a complex and sensitive process. Current separation and purification methods can be divided into three basic steps: (1) cell lysis, in which cells are broken open to release the nucleic acids, (2) clearing of the lysate, which involves the removal of insoluble cellular debris from the soluble nucleic acids, and (3) purification, which involves the separation of the target nucleic acids from other soluble contaminants.

There are several traditional methods to perform each of the three steps required for nucleic acid separation and purification. Cell lysis can be achieved either mechanically or with chemicals, followed by clearing of the lysate, usually by centrifugation. Purification of the nucleic acids can be performed through a variety of methods, which can

be used either alone or in combination, depending on the requirements of the application. The traditional purification methods are phenol extraction, cesium chloride density gradient centrifugation, and precipitation. Phenol extraction is the most commonly used traditional method for nucleic acid purification. Although this method uses inexpensive materials, it is time consuming and labor intensive, requires considerable technical skill, uses hazardous reagents which are increasingly expensive to dispose of, and produces only medium-purity

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nucleic acids. Cesium chloride density gradient centrifugation is used to prepare large amounts of highly pure DNA. However, this method requires two time consuming rounds of separation (24-48 hours in total) in expensive ultracentrifuge equipment, demands substantial technical skill, and involves the use of hazardous reagents. Precipitation is often used to separate nucleic acids from proteins and other contaminants by centrifugation, using chemicals that render either the nucleic acids or the contaminants insoluble. This procedure is fast, inexpensive, and suitable for high-throughput processing, but provides very crude separation and therefore limited purity.

Each of these traditional methods, whether used alone or in combination, has significant limitations. High purity can only be achieved by using hazardous reagents and expensive equipment, while the more convenient and safe methods suitable for high-throughput processing result in reduced purity.

### 2. Technical Overview of QIAGEN

#### Nucleic Acid Separation and Purification Technologies

QIAGEN has developed a core set of technologies to provide a comprehensive approach to the nucleic acid separation and purification process. These technologies can be used alone or in combinations to achieve the best solution for a given application. In particular, the Company's proprietary technologies for solid-phase anion-exchange purification and selective adsorption to silica particles or membranes significantly enhance the purification step, the most difficult, critical, and labor intensive step in the nucleic acid separation and purification process. QIAGEN believes that its 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.

**Solid-Phase Anion-Exchange Technology.** QIAGEN's patented anion-exchange technology was specifically developed for nucleic acid purification. This technology involves selective binding of nucleic acids to a macroporous silica particle coated with a very high density of positively charged anion-exchange groups. Nucleic acids bind tightly to this surface, which allows contaminating substances to be efficiently washed away. After washing, the binding is selectively reversed to release different classes of ultrapure DNA or RNA. QIAGEN believes that its anion-exchange technology is widely viewed as state-of-the-art for obtaining ultrapure nucleic acids. QIAGEN's anion-exchange technology also offers the additional benefits of convenience, speed, reproducibility, and high yield. Techniques that require the use of ultrapure nucleic acids include transfection, microinjection, and gene therapy research. QIAGEN's anion-exchange technology is employed in a number of its products, including QIAGEN(R) Plasmid Kits, QIAfilter(R) Plasmid Kits, EndoFree(R) Plasmid Kits, and QIAwell(R) Plasmid Kits. (See "QIAGEN Products" below for specific product discussions.)

QIAGEN has also developed a new anion-exchange resin, QIAGEN Anion-Exchange Resin HS, with a higher binding capacity for nucleic acids. This development in conjunction with a new tip design, the QIAprecipitator unit, which allows recovery of DNA without centrifugation, and the QIAfilter unit (see "Filtration" below) allows a significantly faster purification procedure. These technologies are used in HiSpeed(TM) Plasmid Kits, the first of which was launched in 2000. The Company believes that these kits provide the fastest procedure currently available for isolation of large amounts of ultrapure DNA.

**Selective Adsorption to Silica Particles or Membranes.** QIAGEN's proprietary silica-gel technology is based on the ability to selectively and efficiently adsorb specific types of nucleic acids to silica-gel particles or membranes in order to separate them from contaminating substances. This technology is particularly suitable for use in molecular biology applications

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where price, speed, and throughput are more important than ultrapurity, such as DNA minipreparations and DNA cleanup for screening, cloning, and PCR. QIAGEN employs this technology in a number of its products, including QIAprep(R), QIAwell; QIAamp(R), QIAquick(R), MinElute(TM), QIAEX(R), DNeasy(R), and RNeasy(R) Kits. QIAGEN has also developed silica-coated magnetic beads and new cell lysis chemistries to allow streamlined automated purification of nucleic acids using silica-based technology. This technology is employed in MagAttract(TM) 96 Miniprep Kits, the first of which was launched in 2001, and is particularly useful for high-throughput genomics and screening. In October of 1997, Organon Teknica, B.V. granted QIAGEN a world-wide, non-exclusive license to develop, manufacture, and market products for nucleic acid purification under its 'Boom' patents (U.S. 5,234,809, and corresponding patents or applications). The license allows QIAGEN to sell products including technologies under these patents in all markets and for all applications, with no field-of-use limitations. The Company believes that the 'Boom' patent portfolio covers a simple, rapid, and flexible nucleic acid purification technology which in combination with silica-based and other technologies proprietary to QIAGEN can create a highly efficient and

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automatable package for a range of nucleic acid purification applications for research, genomics, and molecular diagnostic purposes.

**Cationic Detergent Technology.** Cationic detergents stabilize samples, increasing the reliability and potential of nucleic acid-based molecular diagnostics, particularly assays based on RNA, which is highly unstable. Cationic detergent technology also allows for efficient purification of nucleic acids and is ideal for a clinical environment since it is non-hazardous. QIAGEN has acquired issued and pending patents for a novel cationic detergent technology which performs two important functions in DNA and RNA isolation. When added to plasma, blood, or other clinical specimens, it causes cells, viruses, and bacteria to break open and then forms insoluble complexes with the released DNA and RNA. These DNA and RNA complexes are protected from degradation and can be safely transported or stored. The DNA and RNA are easily recovered from these complexes and immediately ready for use in diagnostic and other reactions.

**Filtration.** QIAGEN has introduced proprietary rapid filtration technology for clearing of the lysate in a single step process that takes just five minutes. The filtered cell lysate containing nucleic acids can then be immediately purified using QIAGEN's anion-exchange or silica-gel-membrane technologies. QIAGEN's filtration technology replaces the time-consuming centrifugation process, which is difficult to automate and does not allow high-throughput sample processing. QIAGEN employs filtration technology in its QIAfilter, TurboFilter, and R.E.A.L.(TM) products, which substantially increase productivity in DNA sequencing and nucleic acid-based molecular diagnostics where high-throughput nucleic acid purification is required, as well as in large-scale production of nucleic acids for genetic vaccination and gene therapy. The R.E.A.L. product line was expanded in 2001 with the introduction of a kit that allows semi-automated purification of plasmid DNA in a 384-well format for very high-throughput requirements. Filtration technology is also used in some protein purification products.

**Magnetic Particle Technologies.** Magnetic particle-based products uniquely combine requirements in the rapidly growing genomics, proteomics and cellomics markets. Certain forms of cell separation and protein separation required in cellomics and proteomics are closely linked with nucleic acid purification, in both research and clinical applications. Therefore, products which link the technologies will offer significant advantages for users in these markets, who will benefit all the more because the products will be optimized to

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share the same QIAGEN BioRobot automation platforms. Magnetic particles are seen by QIAGEN to have applicability in certain segments of nucleic acid purification and have therefore already been one of many technologies incorporated in the broad portfolio of QIAGEN nucleic acid purification products today.

**Hybrid Capture on Polystyrene-Latex Beads.** QIAGEN has obtained a worldwide (except for Japan) exclusive license for a patented technology for hybrid capture on polystyrene-latex beads. Hybrid capture allows isolation of specific nucleic acid sequences directly from a crude biological sample containing a variety of nucleic acids and other contaminants by hybridization to a complementary sequence attached to an insoluble particle. Hybrid capture on polystyrene-latex beads is an innovative system which, in comparison to traditional hybrid capture on cellulose, increases both the speed and efficiency of purification of specific nucleic acid sequences. The most typical application for hybrid capture is the isolation of mRNA. QIAGEN applies this technology in its Oligotex(R) Kits.

**Endotoxin Removal.** QIAGEN has developed a proprietary system that incorporates effective endotoxin removal into the purification process. Endotoxins are produced in bacteria and often appear in trace amounts in purified nucleic acids, since they cannot be effectively removed by most nucleic acid purification systems. Although low-level endotoxin contamination has little or no effect on most molecular biology procedures, even trace amounts can induce toxic reactions in humans. Therefore, nucleic acids for human use must be endotoxin-free. QIAGEN's selective endotoxin removal technology uses a special reagent system in conjunction with the Company's anion-exchange resin and reduces endotoxin contamination of nucleic acids to a level well below the maximum level allowed by the FDA for use in genetic vaccination and gene therapy. QIAGEN employs this technology in its line of EndoFree Plasmid Kits and its contract non-cGMP and cGMP DNA production services.

**RNA Stabilization.** QIAGEN has acquired and developed a technology portfolio covering the use of certain cationic detergents for the stabilization and purification of nucleic acids from certain samples. QIAGEN also acquired a non-exclusive license from AMBION, Inc. for RNAlater technology, which allows stabilization of RNA in animal cells and tissues for reliable gene-expression and gene-profiling analysis. These technologies are used in a new product range -- RNeasy Protect Kits -- that was launched in 2000. A new product line, RNeasy Protect Bacteria Kits, was released in 2001. RNA stabilization technology is also used in the PAXgene(TM) Blood RNA System from PreAnalytiX, a joint venture between BD and QIAGEN that provides integrated and standardized systems for the collection and stabilization of clinical samples together with efficient methods for nucleic acid isolation. The PAXgene Blood RNA System, which is the first PreAnalytiX(TM) product line, was launched in 2001. Stabilization of RNA within biological samples is especially important for the molecular diagnostics market. These products are also used in the molecular biology research market.

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### Other Technologies

**PCR Amplification and Reverse Transcription.** QIAGEN has obtained an exclusive license for the use of a novel reagent for the optimization of PCR amplification, and has developed a proprietary PCR buffer that increases the robustness of the amplification process and makes it less sensitive to variable factors and contaminants. The Company acquired a non-exclusive license to sell reagents for PCR to the research market in November 1995. PCR amplification is one of the most widely used techniques in molecular biology research, and is an important technology for the development of the nucleic acid-based molecular diagnostics market. QIAGEN employs its PCR enhancement technologies in its Taq

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DNA Polymerase, HotStarTaq(TM) DNA Polymerase, and Q-solution products. In 2001, QIAGEN launched ProofStart(TM) DNA Polymerase for high-fidelity PCR, an application in which highly accurate DNA amplification is required. To address the needs of researchers transcribing RNA into DNA for PCR analysis, QIAGEN has developed two recombinant reverse transcriptase enzymes, Omniscript(TM) and Sensiscript(TM), from a new source. The Company also introduced the QIAGEN OneStep RT-PCR Kit which combines its reverse transcriptase and HotStarTaq DNA Polymerase enzymes with a novel patent-pending buffer system to provide a complete RT-PCR assay system. Real-time PCR, a relatively new PCR-based technique that allows quantification of target DNA or RNA species, is becoming more and more widely used in both molecular biology research and clinical diagnostics. To address this field, in 2001 QIAGEN launched the QuantiTect(TM) SYBR(R) Green PCR and RT-PCR System, which incorporates HotStarTaq DNA Polymerase, an optimized blend of Omniscript and Sensiscript RT, and a specifically designed buffer. The QuantiTect SYBR Green PCR and RT-PCR System can be used with any real-time PCR cyclers for accurate quantification of DNA, cDNA, and RNA targets, and is an important new line that addresses a rapidly expanding market.

Transfection. The Company has obtained exclusive licenses for several patented technologies for high-efficiency transfection of DNA and RNA into cultured eukaryotic cells. Transfection is the process by which foreign nucleic acids are transferred into living cells. The efficiency of the transfection process is heavily dependent upon the purity of the nucleic acid, the nature of the cells, and the type of transfection reagent used, and poor transfection efficiencies can result in weeks of wasted time. The novel activated dendrimer technology licensed to QIAGEN is employed in the Company's PolyFect(R) and SuperFect(R) Transfection Reagents. The Company's other two transfection reagents, Effectene(R) and TransMessenger(TM) Transfection Reagents, are based on a novel lipid formulation technology licensed exclusively to QIAGEN. PolyFect, SuperFect, and Effectene Reagents are designed for transfection of different types of cells with DNA, while TransMessenger Reagent, launched in 2001, is the first reagent specifically developed for transfection of cells with RNA. All reagents provide increased transfection efficiency in many cell types compared to traditional transfection methods and decrease the amount of cell death during the transfection process. With these two transfection technologies, QIAGEN believes it addresses the needs of researchers transfecting a wide range of cell types with either DNA or RNA.

Metal Chelate Affinity Chromatography. QIAGEN has obtained an exclusive license for a patented affinity purification system for recombinant proteins, which allows rapid one-step purification of proteins labeled with a specific affinity "tag." QIAGEN's proprietary metal chelate affinity chromatography system uses a patented high affinity chelating ligand (the NTA ligand), which provides highly efficient detection and purification of specific recombinant proteins carrying an affinity tag. These tagged recombinant proteins can be produced with the Company's proprietary bacterial expression system or any other expression system. QIAGEN believes that the high affinity of its NTA ligand provides significant advantages over other metal chelate systems in terms of purity, speed and convenience. QIAGEN has developed additional NTA metal chelate affinity systems for color-based detection of specific recombinant proteins, and for directional immobilization of antigens onto solid surfaces for screening purposes. QIAGEN employs this technology in its line of QIAexpress products. In 2001, the Company expanded its expression (see "DNA Cloning", below) and detection systems for tagged recombinant proteins, and introduced a new system for efficient removal of the tag for certain applications. This new system, the TAGzyme(TM) System, employs technology obtained from an exclusive license.

DNA cloning. QIAGEN has obtained a license for UA cloning technology, which allows insertion of a PCR product into a plasmid DNA vector for subsequent experiments. DNA cloning is a widely used, routine technique in molecular biology. UA cloning technology offers advantages over other DNA cloning

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technologies, such as a faster procedure, and is used in the plasmid DNA vectors supplied in the QIAexpress UA Cloning Kit and QIAGEN PCR Cloning Kits. The Company has also obtained a license for highly competent bacterial cells, which are used as part of the cloning procedure. These cells are provided with QIAGEN PCR Cloningplus Kits to further address the needs of researchers performing such experiments. QIAGEN has additionally obtained a license for, and further developed, a DNA vector that allows expression of proteins in E. coli, insect, and mammalian cells, the three most popular systems for protein expression.

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Masscode(TM) System. Through the acquisition of Rapigene, Inc. (now QIAGEN Genomics, Inc.), QIAGEN has acquired the patents to Masscode Cleavable Mass Spectrometry Tag technology. This is the first new DNA tagging technology since the discovery of four-color fluorescence. Unlike fluorescence, which is limited to 4-8 analyses at a time, Masscode tags are capable of providing hundreds of simultaneous measurements. In the field of genomic analysis, use of Masscode technology coupled with a standard single-quadrupole mass spectrometer allows over 40,000 measurements to be made per day per instrument. This technology provides highly reliable, reproducible, and cost-efficient SNP genotyping, at what QIAGEN believes to be an unmatched speed and quality. The technology is validated and offered world-wide as a service by QIAGEN Genomics, Inc. to leading pharmaceutical, agricultural, and genomics companies, as well as academic centers. In addition, QIAGEN Genomics, Inc. has built a range of enabling technologies that can create further powerful packages in combination with certain of QIAGEN's products. These include innovative, enabling technologies that increase the efficiency of handling of nucleic acid microarrays, also known as biochips, and technologies that dramatically improve and control the hybridization reactions incorporated in many types of DNA assays including biochips.

Synthetic DNA. Through the acquisition of California-based Operon Technologies, Inc. in June, 2000, QIAGEN has acquired a technology platform for massive parallel, high-throughput DNA synthesis which offers significant advantages for primer and probe synthesis as well as "longmer" synthetic nucleic acids of up to 100 bases that can be used for construction of synthetic DNA genes, full-length genes, or enhanced DNA microarray tools. Based on a better binding affinity, QIAGEN Operon's high-throughput synthesis technology platform allows the manufacture of synthetic nucleic acids at unparalleled speed, cost, and quality. A second production site in Germany commenced operations in 2001.

Resonance Light Scattering. Licensed by QIAGEN from Genicon Sciences Inc. RLS Technology is an ultra-sensitive signal generation, multi-application platform and detection technology for the simple and efficient detection, measurement and analysis of biological interactions. By using these proprietary "nano-sized" particle labels that specifically bind to targeted molecules, minimal sample amounts of targeted nucleic acids and proteins can be measured by simple, low cost white light source-based instrumentation. The ultra-high sensitivity of RLS Technology allows researchers to access novel biological information and avoid time-consuming, expensive and information-distorting amplification procedures such as PCR.

Planar Waveguide (PWG) Technology. Licensed by QIAGEN from Zeptosens AG, this technology allows the use of minimal sample amounts for analysis of the differential expression pattern of genes that are expressed at very low levels. Its extremely high sensitivity allows users to avoid cumbersome, expensive, and information-distorting amplification procedures such as PCR. The PWG Chip and the reader systems are combined with certain of QIAGEN's leading nucleic acid separation, purification, and handling technologies to form a complete, integrated analysis line for microarray experiments.

3. QIAGEN's Products

QIAGEN offers over 300 products, which include a broad range of consumables as well as instruments and services, for a variety of applications in the separation, purification, and subsequent use of nucleic acids. These products enable QIAGEN's customers to efficiently pursue their research and commercial goals that require the use of nucleic acids. Major applications for the Company's consumable products are plasmid DNA purification; nucleic acid transfection; RNA stabilization and purification; genomic and viral nucleic acid purification (principally for PCR); PCR amplification; reverse transcription; DNA cleanup after PCR and sequencing; and DNA cloning. QIAGEN offers most of these products in kit form to maximize customer convenience and reduce user error. These kits contain QIAGEN's proprietary disposable separation and purification devices and/or other proprietary technologies, all 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 one thousand. Each kit is covered by the Company's quality guarantee. QIAGEN's BioRobot(R) Systems perform automated nucleic acid preparation and reaction set-up, providing customers with the ability to perform high-throughput and reliable DNA sample preparation and other laboratory tasks. QIAGEN also offers custom services, including SNP genotyping and analysis, DNA sequencing, and non-cGMP and cGMP DNA production on a contract basis. In addition, the Company offers specialized products for protein expression, purification, detection, and analysis, as well as for immunization for production of antibodies. These products complement the Company's nucleic acid separation and purification technologies and products.

Consumable Nucleic Acid Separation and Purification Products

QIAGEN offers a wide range of consumable nucleic acid separation and purification products based on its platform of proprietary technologies. These are targeted to a number of nucleic acid purification applications and markets as set forth below.

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Plasmid DNA Purification. Plasmid DNA purification is the most common and basic technique in molecular biology, encompassing a wide range of quality, throughput, and pricing needs. Plasmid DNA is a small circular piece of bacterial DNA capable of moving from one cell to another. This property, in conjunction with an ability to acquire new pieces of genetic information (recombination), makes plasmid DNA a basic prerequisite for cloning, sequencing, transfection, and many other molecular biology applications.

QIAGEN offers a wide range of products for plasmid DNA purification, each tailored to the needs of a specific application. For convenient, large-scale preparation of ultrapure plasmid DNA, the Company offers QIAGEN, QIAfilter, and EndoFree Plasmid Kits, which are based on the Company's proprietary anion-exchange, filtration, and endotoxin removal technologies. In 2000, QIAGEN introduced the first HiSpeed Plasmid Kit, which has a newly developed anion-exchange resin and tip design as well as QIAfilter technology for clearing cell lysates and new QIAprecipitator(TM) technology for recovering DNA without the need for centrifugation, making the purification procedure significantly faster. Kits for purification of ultrapure plasmid DNA are used in the molecular biology research, DNA sequencing, and genetic vaccination and gene therapy research markets, and range in price from \$155 to \$1,362 per kit. QIAGEN believes that future applications for these products will be large-scale plasmid purification for the commercial genetic vaccination research and gene therapy research markets.

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QIAGEN offers a comprehensive range of products for plasmid DNA minipreparations (purification of small amounts of DNA). QIAwell Plasmid Kits, based on the Company's anion-exchange and filtration technologies, are available in 8-well and 96-well formats for high-throughput minipreparations of ultrapure plasmid DNA for transfection, sequencing, and other sensitive molecular biology applications. QIAprep Miniprep Kits, based on the Company's proprietary silica-gel-membrane and filtration technologies, are available in single column, 8-well, and 96-well formats for low- to high-throughput minipreparations of high-purity plasmid DNA for standard molecular biology applications such as sequencing, cloning, and PCR. R.E.A.L. Prep 96 and microR.E.A.L. Prep 384 Plasmid Kits use the Company's filtration technology to provide fast and economical minipreparations for very high-throughput screening and DNA sequencing projects. The MagAttract 96 Miniprep System, released in 2001 and based on the Company's proprietary silica, cell lysis, and magnetic bead technologies, allows fully automated, high-throughput plasmid DNA purification for high-throughput genomics and screening applications. QIAGEN miniprep products range in price from \$60 to \$3,400 per kit. QIAGEN believes that applications for these products will expand with the development of molecular biology research, DNA sequencing, and genomics markets.

Genomic and Viral Nucleic Acid Purification. Reliable clinical diagnostics and genetic analysis require reproducible preparation of genomic and viral nucleic acids as the templates for the PCR amplification process that frequently precedes a diagnostic procedure. For purification of these nucleic acids from starting materials such as blood, tissue, mucus, or stool, QIAGEN offers a comprehensive range of QIAamp Kits, which use its silica-gel-membrane technology and proprietary cell lysis procedures. These products are available in both single column and 96-well formats and are used in the molecular biology and molecular diagnostic research markets. They range in price from \$94 to \$2,075 per kit. QIAGEN believes that future applications of these products for PCR template purification will expand significantly with the commercialization of the nucleic acid-based molecular diagnostics market and will include gene-based drug screening.

RNA Stabilization and Purification. RNA purification requires rapid and efficient removal of contaminants that can destroy fragile RNA molecules. For rapid RNA purification, QIAGEN offers the RNeasy(R) product line, which uses its silica-gel-membrane technology in both single column and 96-well formats. For specific purification of mRNA, QIAGEN offers Oligotex Kits based on its proprietary technology for hybrid capture on polystyrene-latex beads. These products are used in the molecular biology and molecular diagnostic research markets and range in price from \$90 to \$957 per kit.

In 2000 QIAGEN introduced the first in a series of planned products that allow stabilization of RNA within biological samples, which is especially important for the molecular diagnostics market. RNA becomes extremely unstable once a biological sample is harvested, as expression of some genes is induced by the collection (leading to more RNA for those genes) and other RNA species become degraded after collection. Immediate stabilization of the RNA and preservation of the RNA expression pattern is therefore a prerequisite for accurate gene-expression analysis. RNeasy Protect Kits, launched in 2000, combine RNeasy and RNAlater(TM) technologies. The latter technology, for which the Company acquired a non-exclusive license from AMBION, Inc., allows stabilization of RNA in animal tissues for reliable gene-expression and gene-profiling analysis. RNAlater RNA Stabilization Reagent is also available as a separate product for sample stabilization, and can be used in conjunction with all RNA purification kits available from QIAGEN. In 2001, QIAGEN introduced a new product line that allows stabilization of RNA in bacterial cells -- RNeasy Protect Bacteria Kits. These products are used in the molecular biology and molecular diagnostic research markets and range in price from \$47 to \$951 per kit. PreAnalytiX, a joint venture between BD and QIAGEN that provides integrated



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and standardized systems for the collection and stabilization of clinical samples

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together with efficient methods for nucleic acid isolation, released its first product line in 2001 -- the PAXgene Blood RNA System. Blood samples are collected in PAXgene Blood RNA Tubes, in which they can be stored or transported at room temperature without RNA degradation or gene induction, and RNA is isolated from the sample using a standardized procedure. This new system is particularly relevant to the pharmaceutical industry and the clinical research market, and kits are priced between \$160 and \$600. QIAGEN believes that applications for its RNA stabilization and purification products will expand significantly as the molecular diagnostics market adopts nucleic acid-based testing.

DNA Cleanup. DNA cleanup products are used to remove reagents and contaminants, such as primers, nucleotides, and enzymes, from DNA fragments amplified by PCR or modified by other enzymatic reactions before they are used in cloning, sequencing, microarray analysis, or other downstream applications. QIAGEN offers a range of QIAquick and QIAEX Kits in single column, 8-well, and 96-well formats for specific cleanup applications. In 2000, QIAGEN launched a new range of cleanup kits, MinElute Kits, which use a new spin-column design developed at QIAGEN to allow elution of DNA fragments in a much lower volume than previously possible. MinElute, QIAquick, and QIAEX Kits are based on QIAGEN's silica-gel technology and are used in the molecular biology research, DNA sequencing, and molecular diagnostic research markets. These kits range in price from \$78 to \$600 per kit. QIAGEN also offers DyeEx(TM) Kits -- available in single column and 96-well formats -- for cleanup of sequencing samples prior to analysis. These kits are used in the molecular biology research and DNA sequencing markets, and range in price from \$110 to \$1,450 per kit. QIAGEN believes that applications for its DNA cleanup products will expand as the microarray, DNA sequencing and molecular diagnostics markets continue to develop.

### Consumable Enzymes and Reagents

PCR and RT Enzymes and Reagents. PCR and reverse transcription (RT), and RT-PCR have become a widely used tool for amplification of nucleic acids in molecular biology, making them easier to detect. As a result, a profitable market segment has developed for companies licensed to sell products covered by PCR-related patents. In November 1995, the Company acquired a non-exclusive license from Hoffmann-La Roche for the use, production, and sale of enzymes and reagents required for PCR in the research market. This license allows QIAGEN to market kits that include its existing products for pre-PCR sample preparation and post-PCR DNA cleanup bundled with PCR enzymes and reagents. The Company believes it is well situated to penetrate the rapidly growing PCR research market by capitalizing on its leadership position in sample preparation and its reputation for innovative and high quality products. The PCR license therefore allows the Company to offer customers in the research market a fully integrated solution to their nucleic acid purification and amplification needs. QIAGEN launched its first two PCR products in November 1996 and has followed this with a range of additional kits for standard and specialized PCR applications, including the launch in 2001 of a new high-fidelity DNA polymerase that allows highly accurate DNA amplification. The Company's PCR products range in price from \$88 to \$1,664 per kit. QIAGEN has also entered the reverse transcription (RT) market. RT is the process by which RNA is transcribed into DNA for subsequent analysis, most frequently PCR analysis. QIAGEN offers a line of enzymes and kits for RT and RT-PCR, including a new one-step RT-PCR kit launched in 2000, which range in price from \$42 to \$623 per kit. Real-time PCR, a new

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PCR-based technique that allows quantification of target DNA or RNA species, is becoming more and more widely used in both molecular biology research and clinical diagnostics. To address this field, in 2001 QIAGEN launched the QuantiTect SYBR Green System, which incorporates the Company's PCR and RT enzymes and reagents. This system can be used with any real-time PCR cyclers for accurate quantification of DNA, cDNA, and RNA targets, and is an important new line that addresses a rapidly expanding market. Kits range in price from \$330 to \$655. The Company believes there is significant potential for these products in molecular biology research and molecular diagnostics markets.

DNA Cloning. Cloning of DNA into plasmids is a routine and basic molecular biology method. As described above, plasmids are small circular pieces of bacterial DNA into which new pieces of DNA can be introduced, a technique called cloning. In 2001, QIAGEN introduced new products that use UA-cloning technology for fast and easy insertion of a PCR product into a plasmid DNA. These new products extend the range of products that QIAGEN offers to researchers performing PCR, and are priced between \$62 and \$572.

DNA Transfection Reagents. QIAGEN identified a new product opportunity in the transfection of plasmid DNA into mammalian cells, which is currently the major application for ultrapure plasmid DNA purified with QIAGEN products. The Company has obtained exclusive licenses for several innovative reagents for efficient transfection, and offers a range of reagents that address specific market needs. QIAGEN currently offers three reagents for transfection of DNA, priced in the range of \$103 to \$720 per kit, with bulk quantities of each reagent also available for high-throughput applications. In 2001, QIAGEN launched the first transfection reagent specifically designed for transfection of cells with RNA. This reagent provides researchers with new possibilities for transfection experiments, and is priced at \$140. QIAGEN Transfection Reagents can be bundled with its existing plasmid and RNA purification products for molecular biology and gene therapy research markets.

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### Instrumentation

Both academic and industrial research laboratories are actively seeking automation of routine procedures to free scientists and technicians for more sophisticated tasks, eliminate human error, and increase throughput. This demand for automation is being fueled by the DNA sequencing market, the Human Genome Project and other genome projects, gene-based drug screening, and nucleic acid-based molecular diagnostics, all of which require tremendous numbers of routine nucleic acid sample preparations and enzymatic reactions. In response to this market demand, QIAGEN offers the BioRobot(R) product line. The QIAGEN BioRobot 9600 is a benchtop workstation specifically designed to automate routine liquid-handling tasks as well as nucleic acid and protein purification, complete with pre-programmed software for automation of many QIAGEN purification procedures, such as QIAwell, QIAprep, R.E.A.L., and QIAquick. The current list price of a BioRobot 9600 is \$54,100. The BioRobot 9600 is used in the molecular biology research, molecular diagnostic research, and DNA sequencing markets. The second instrument introduced, the BioRobot 9604, targets nucleic acid sample preparation and handling tasks in molecular diagnostics laboratories, blood banks, and forensic projects. Nucleic acid samples purified on the BioRobot 9604 are ready for use in the demanding and sensitive downstream assays performed in molecular diagnostic, pharmaceutical, and research applications. The current list price of the BioRobot 9604 is \$92,900. In August 1999, the Company introduced the QIAGEN BioRobot 3000. The BioRobot 3000 offers a completely flexible approach to automation, with each instrument being tailor-made to the individual laboratory's application needs. The BioRobot 3000 is used in molecular biology research, molecular diagnostic research, DNA sequencing, and

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genomics markets. Since the BioRobot 3000 is a custom instrument, the price depends on what components are installed and what base model is selected. The base prices, without any added components, are \$42,200 for a 4-probe 90 cm system, \$47,500 for the 4-probe 120 cm system and \$58,300 for the 4-probe 200 cm system. The BioRobot RapidPlate(TM), which can be fully integrated with BioRobot 3000 extended arm systems, was introduced in 2001 for fast liquid handling in 96- and 384-well formats. The BioRobot RapidPlate is priced at \$43,000.

In 2000, QIAGEN introduced the BioRobot 8000. The BioRobot 8000 allows high-throughput, walk-away purification of nucleic acids. The fully automated capability is provided by new technologies, such as an automated vacuum system, automated identification and tracking of buffer bottles, and a fast and accurate liquid and robotic handling system. The BioRobot 8000 is designed for routine handling of 384-well formats, and is used by laboratories at the leading edge of genomics and other molecular biology fields. The list price for a BioRobot 8000 is \$99,000.

All BioRobots use QIAsoft(TM) software, which provides user-friendly point-and-click control. New software and hardware upgrades are continuously being developed to improve the speed and performance of the BioRobot series and to expand the range of potential applications.

The BioRobot product line gives QIAGEN a strategic opportunity to establish a large installed instrumentation base, thereby promoting recurring sales of QIAGEN's consumable products. Each installed instrument generates additional annual consumable sales of approximately \$22,800 to \$64,800. QIAGEN provides several consumable products for use with BioRobots based on existing QIAamp, RNeasy, and protein purification kits. Two new kits were introduced in 2001, based on filtration technology and silica-coated magnetic bead technology. The Company believes future markets for these instruments will include the molecular diagnostic and genomics markets.

In addition to the BioRobot Product line, QIAGEN also offers liquid handling instrumentation products that are not coupled with nucleic acid purification uses to OEM customers. This allows QIAGEN to spread the cost of designing and manufacturing the instrumentation products over a larger unit volume.

Instrumentation products account for less than 15 percent of QIAGEN's total consolidated net sales.

### Contract Services

QIAGEN offers contract services for non-cGMP DNA production, SNP analysis services, and DNA sequencing as an additional way to market its products, and to expand and promote its technologies. All services are provided with full project consultation and support from experienced technical staff.

Plasmid DNA Contract Manufacturing Service. Most customers who require the ultrapure DNA provided by QIAGEN products are usually not equipped to produce it in the large amounts necessary for their pre-clinical and clinical studies. QIAGEN offers these customers contract DNA production under non-cGMP conditions and using its proprietary technology for ultrapure DNA purification and endotoxin removal, suitable for all preclinical research as well as for preclinical studies in gene therapy and genetic vaccination.

cGMP-grade plasmid DNA is required by the FDA and other regulatory agencies for any application involving use in humans. QIAGEN joined an alliance

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with Valentis Inc. and DSM Biologics in 1999 to further strengthen what is considered the world's leading consortium for manufacturing and supplying customers with contract manufacturing of ultrapure, stable DNA plasmids and formulated cGMP-grade DNA at any scale, from preclinical toxicology studies to commercial products. This alliance provides a quality and scale of cGMP-grade plasmid DNA production that the Company believes is unsurpassed by any other supplier. Customers may include pharmaceutical or biotech companies or academic institutions working in the gene therapy and genetic vaccination fields. QIAGEN shares in revenues and profits from this alliance. Valentis Inc. (resulting from the merger of Megabios Corp. and GeneMedicine, Inc.) is a leader in the field of gene medicines. The Company develops proprietary gene delivery systems and applies its preclinical and early clinical development expertise to create gene-based products. DSM Biologics, a unit of DSM Fine Chemicals, is a leading development and manufacturing company of intermediates and active pharmaceutical ingredients for the pharmaceutical industry.

SNP analysis and DNA sequencing services. QIAGEN Genomics, Inc. (formerly Rapigene, Inc.) offers high-throughput single nucleotide polymorphism (SNP) genotyping, SNP validation services, and products based on its Masscode(TM) technology. This proprietary technology represents a new dimension in screening of genetic variations (SNPs) between individuals. Masscode technology is the first new DNA tagging technology since the discovery of four-color fluorescence. Unlike fluorescence, which is limited to 4-8 analyses at a time, Masscode tags are capable of providing hundreds of simultaneous measurements. In the field of genomic analysis, use of Masscode technology coupled with a standard single-quadrupole mass spectrometer allows over 40,000 measurements to be made per day per instrument. This technology provides highly reliable, reproducible, and cost-efficient SNP genotyping, at what QIAGEN believes to be an unmatched speed and quality. Furthermore, this technology platform has tremendous headroom for next generation developments. The technology is validated and currently offered world-wide as a service by QIAGEN Genomics, Inc. to leading pharmaceutical, agricultural, and genomics companies, as well as academic centers. QIAGEN Genomics, Inc. also offers SNP discovery, DNA isolation, and DNA quantification services.

In 2000, QIAGEN Genomics, Inc. formed an alliance with Genomics Collaborative, Inc., a company that has built a state-of-the-art repository of human DNA, tissue, and serum samples linked to detailed medical and demographic data from selected populations. This alliance offers an integrated solution combining Genomics Collaborative, Inc.'s sample repository and database services with QIAGEN Genomics' SNP genotyping services. In January, 2001 QIAGEN Genomics, Inc. extended its collaboration with Genomics Collaborative, Inc. and in addition formed two further agreements with Agilent Technologies, Inc. and Daiichi Pure Chemicals, Co. Ltd., as well as a research agreement with the University of Washington to develop further high-throughput genomic analysis for applications in areas including services and drug discovery.

QIAGEN Genomics offers a Genomic DNA Isolation Service for purification of high-quality DNA that is suitable for all genomics and molecular biology applications as well as for archiving. Versatile QIAamp(R) and DNeasy(R) Systems allow isolation of genomic DNA from a variety of sources (e.g., blood, mouth washes, and animal and plant tissue) at all scales, from just a few micrograms to several milligrams of genomic DNA.

QIAGEN Genomics also offers medium to high-throughput DNA sequencing services, which use QIAGEN's proprietary DNA purification and automation technologies as well as state-of-the-art, high-throughput, automated sequencing technologies. The current capacity is >700 Mb of raw data per year, and further expansion is planned for 2002. QIAGEN has already contributed to several commercial and public large-scale DNA sequencing projects, including several eukaryotic, viral, and bacterial genome projects, as well as the full-length human cDNA project. QIAGEN also provides a bioinformatics system,

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ConSequence(TM), for analysis of DNA sequences.

QIAGEN's contract services, which account for less than ten percent of total consolidated net sales, are currently provided to the molecular biology and genomics research market for genetic vaccination, gene therapy, pre-clinical trials, SNP genotyping, and DNA sequencing. The Company expects future markets for these services to be expanded to include molecular diagnostics and genomics.

### Oligonucleotide Synthesis, Microarray Products, and Custom Gene Synthesis

QIAGEN Operon (QIAGEN Operon, Inc. and QIAGEN Operon GmbH) is a recognized leader in the area of high-end and added-value synthetic DNA. Operon provides custom DNA synthesis of oligonucleotides using a revolutionary high-throughput synthesis platform. A large number of oligonucleotide-modification options are available. QIAGEN Operon also provides a range of arrayable oligonucleotide sets (Array-Ready Oligo Sets(TM)) for the genome of several species, including human, yeast (*Saccharomyces cerevisiae*), tuberculosis (*Mycobacterium tuberculosis*), malaria (*Plasmodium falciparum*), mouse, rat, arabidopsis (*Arabidopsis thaliana*), *Caenorhabditis elegans*, and *Candida albicans*, with more sets planned for release. These sets represent the genomes of either

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clinically relevant or widely used model organisms. QIAGEN Operon can also provide custom arrays of oligonucleotides or other DNA fragments. QIAGEN Operon additionally provides a custom gene synthesis service for the manufacturing of genes for pharmaceutical and biotechnology applications as well as a range of stock oligonucleotide products.

QIAGEN Operon's leading US technology and market position in high-quality, high-precision, and high-throughput synthetic nucleic acids, as well as opportunities for new and powerful joint products, is expected to allow significant expansion into the dynamic areas of today's genomics and genetic analysis markets.

### Recombinant Protein Purification Products

Purification of recombinant proteins is a necessary step in most molecular biology research projects, and is therefore performed by most of QIAGEN's customer base. QIAGEN offers its customers the QIAexpress(R) products, which use a unique purification technology based on metal chelate affinity chromatography on Ni-NTA resin for one-step purification of recombinant proteins. The QIAexpress line also includes products for protein expression and a proprietary protein detection system based on metal chelate affinity technology. Several new products were introduced in 2001, including new vectors for expression of recombinant proteins as well as new antibodies for their detection, and a new system for cleaving the tag (used in the purification technology) from recombinant proteins for specialized applications. QIAexpress products are used in the molecular biology and molecular diagnostic research markets, and cost between \$73 and \$3,224. QIAGEN believes that applications for these products will expand with growth in the genomics and proteomics markets.

#### 4. Product Development

QIAGEN's product development efforts are focused on expanding its existing products and developing innovative new products in selected areas where it has expertise and has identified substantial unmet market needs. In order to increase the efficiency of product development a matrix structure was implemented into the research and development organization during 2001.

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The global research and development activities in Germany, Switzerland and USA are overseen by a Vice President of Research & Development, and consist of six Directors and fifteen Associate Directors. The total number of research and development employees is 328. Research and product development activities related to synthetic DNA and SNP analyses are conducted primarily in the U.S. at the Company's Alameda, California and Bothell, Washington facilities, respectively. Twenty research staff members conduct research and product development activities related to synthetic DNA, five of whom have PhD's, and whom three product managers oversee. The team that oversees the research and development activities related to technologies and services for SNP analyses and other genomic applications includes two business development directors (PhD's), nine managers (two PhD's and one MD), and nineteen research and development staff members.

The Company's total research and development expense 2001 was approximately \$26.8 million. QIAGEN has focused its product development efforts in the following key areas:

### Consumables

QIAGEN intends to maintain its technology leadership position through investments in product improvements, product extensions, and innovative new approaches. Recent examples of its efforts include the introduction of a new range of products for reverse transcription (RT)-PCR, amplification of RNA, stabilization of RNA in biological samples, and high-speed isolation of plasmid DNA, as well as new automated protocols for DNA and RNA isolation from clinical samples using the Company's QIAamp and RNeasy technologies.

### Instrumentation

In 2001, QIAGEN launched new applications for its BioRobot 8000 as a technology platform for automation of nucleic acid separation and purification consumable products. The range of applications that can be performed on the BioRobot 8000 now included HT purification of DNA and RNA using magnetic bead technology. The fully automated capability is provided by new technologies, such as an automated vacuum system, automated identification and tracking of buffer bottles, and a fast and accurate liquid and robotic handling system. The BioRobot 8000 is designed for routine handling of 384-well formats, and is used by laboratories at the leading edge of genomics and other molecular biology fields. QIAGEN believes that improvements in its instrumentation will strengthen its leadership position in the automation of nucleic acid-based applications and generate an increased demand for its consumable products.

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In April 2001, QIAGEN and Zymark Corporation announced a strategic alliance addressing the use of ultra high-throughput sample and liquid handling automation. The alliance will focus on uses of such instrumentation for nucleic acid handling and purification as well as for QIAGEN's proprietary protein expression and purification technology.

### Genomics

As the genomics and drug discovery market expands, there is an increased need for efficient methods to prepare and analyze samples. As this market is often defined by the request for integrated solutions, QIAGEN has leveraged its nucleic acid handling, extraction and purification expertise by entering into a number of transactions and agreements.

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Since the acquisition of Operon Technologies, Inc. a technology leader in the area of massive parallel high-throughput synthesis of nucleic acids, as well as in the area of tools building on synthetic DNA expertise, such as synthetic genes and microarrays tools, Operon Technologies, Inc (since renamed QIAGEN Operon, Inc.), has increased it's high volume synthesis capabilities by new process development steps within the synthesis process. The European operation of QIAGEN Operon GmbH has been established in Cologne, to serve directly the European customers and commenced operations during 2001.

QIAGEN Genomics, Inc. also entered into a research and license agreement in May 2001 with The Institute for Genomic Research (TIGR) and the Montefiore Medical Center (MMC) regarding an association study of single nucleotide polymorphisms (SNPs) in *Mycobacterium tuberculosis* (*M. tuberculosis*).

In 2001, QIAGEN announced collaborations with Genicon Inc. QIAGEN received exclusive distribution rights for self-spotted microarray toolkit products incorporating Genicon's RLS (Resonance Light Scattering) Technology, an ultra-sensitive signal generation, multi-application platform and detection technology. RLS Technology can be combined with QIAGEN's leading nucleic acid sample handling separation and purification products to create an integrated solution for applications including the labeling and analysis of self-spotted nucleic acid microarrays.

In an agreement with Kreatech Biotechnology B.V., QIAGEN was granted an exclusive license to KREATECH