

QIAGEN NV  
Form 6-K  
November 15, 2004  
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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

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## QIAGEN N.V.

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Spoorstraat 50  
5911 KJ Venlo  
The Netherlands

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F

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Form 20-F  Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934

Yes  No

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	<b>September 30,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 143,068,000	\$ 98,993,000
Marketable securities	62,366,000	6,527,000
Notes receivable	3,950,000	5,583,000
Accounts receivable, net of allowance for doubtful accounts of \$2,679,000 and \$3,046,000 in 2004 and 2003, respectively	60,843,000	60,962,000
Income taxes receivable	2,698,000	3,182,000
Inventories	57,484,000	65,160,000
Deferred income taxes	12,097,000	8,094,000
Prepaid expenses and other	12,822,000	10,360,000
<b>Total current assets</b>	<b>355,328,000</b>	<b>258,861,000</b>
<b>Long-Term Assets:</b>		
Property, plant and equipment, net	206,570,000	232,860,000
Long-term marketable securities		498,000
Goodwill	46,887,000	30,117,000
Intangible assets, net	27,943,000	14,521,000
Deferred income taxes	2,616,000	4,604,000
Other assets	18,254,000	10,469,000
<b>Total long-term assets</b>	<b>302,270,000</b>	<b>293,069,000</b>
<b>Total assets</b>	<b>\$ 657,598,000</b>	<b>\$ 551,930,000</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents**QIAGEN N.V.CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>September 30,</u> <u>2004</u>	<u>December 31,</u> <u>2003</u>
	<u>(unaudited)</u>	
Liabilities and Shareholders' Equity		
Current Liabilities:		
Current portion of long-term debt	\$	\$ 7,909,000
Current portion of capital lease obligations	1,104,000	1,320,000
Accounts payable	13,369,000	19,481,000
Accrued and other liabilities	42,213,000	31,344,000
Income taxes payable	6,496,000	23,233,000
Deferred income taxes	5,065,000	11,991,000
	<u>68,247,000</u>	<u>95,278,000</u>
Long-Term Liabilities:		
Long-term debt, net of current portion	200,435,000	100,444,000
Capital lease obligations, net of current portion	12,853,000	13,716,000
Other	8,536,000	7,706,000
	<u>221,824,000</u>	<u>121,866,000</u>
Commitments and Contingencies		
Shareholders' Equity:		
Common shares, .01 EUR par value:		
Authorized 260,000,000 shares		
Issued and outstanding 146,826,449 shares in 2004 and 146,217,518 shares in 2003	1,493,000	1,485,000
Additional paid-in capital	145,359,000	140,039,000
Retained earnings	196,133,000	163,270,000
Accumulated other comprehensive income	24,542,000	29,992,000
	<u>367,527,000</u>	<u>334,786,000</u>
Total liabilities and shareholders' equity	<u>\$ 657,598,000</u>	<u>\$ 551,930,000</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents**QIAGEN N.V.CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net sales	\$ 90,403,000	\$ 90,446,000	\$ 285,098,000	\$ 256,283,000
Cost of sales	29,248,000	31,389,000	94,374,000	87,097,000
Cost of sales acquisition related	1,454,000		1,454,000	
<b>Gross profit</b>	<b>59,701,000</b>	<b>59,057,000</b>	<b>189,270,000</b>	<b>169,186,000</b>
<b>Operating Expenses:</b>				
Research and development	7,641,000	7,538,000	26,270,000	22,670,000
Sales and marketing	20,030,000	20,784,000	65,035,000	60,609,000
General and administrative	9,791,000	11,425,000	31,999,000	31,619,000
Acquisition related costs	572,000		572,000	
Relocation and restructuring costs	763,000		3,509,000	1,567,000
<b>Total operating expenses</b>	<b>38,797,000</b>	<b>39,747,000</b>	<b>127,385,000</b>	<b>116,465,000</b>
<b>Income from operations</b>	<b>20,904,000</b>	<b>19,310,000</b>	<b>61,885,000</b>	<b>52,721,000</b>
<b>Other Income (Expense):</b>				
Interest income	861,000	227,000	1,789,000	667,000
Interest expense	(1,653,000)	(972,000)	(3,645,000)	(3,082,000)
Research and development grants	296,000	984,000	1,209,000	1,681,000
Gain (loss) on foreign currency transactions	56,000	8,000	(201,000)	798,000
Loss from equity method investees	(753,000)	(597,000)	(1,946,000)	(1,264,000)
Other miscellaneous income (expense), net	616,000	63,000	(8,845,000)	59,000
<b>Total other expense</b>	<b>(577,000)</b>	<b>(287,000)</b>	<b>(11,639,000)</b>	<b>(1,141,000)</b>
<b>Income before provision for income taxes</b>	<b>20,327,000</b>	<b>19,023,000</b>	<b>50,246,000</b>	<b>51,580,000</b>
Provision for income taxes	7,687,000	7,258,000	17,383,000	17,717,000
<b>Net income</b>	<b>\$ 12,640,000</b>	<b>\$ 11,765,000</b>	<b>\$ 32,863,000</b>	<b>\$ 33,863,000</b>
<b>Net income per common share:</b>				
Basic and diluted	\$ 0.09	\$ 0.08	\$ 0.22	\$ 0.23

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents**QIAGEN N.V.CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
<b>Cash Flows from Operating Activities:</b>		
Net income	\$ 32,863,000	\$ 33,863,000
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	18,125,000	18,942,000
Provision for losses on accounts receivable	111,000	1,506,000
Deferred income taxes	(11,294,000)	4,450,000
Loss on disposition of synthetic DNA business unit	9,796,000	
Loss on disposition of property and equipment	154,000	442,000
Net realized gain on marketable securities	(523,000)	(191,000)
Loss on equity method investee	1,946,000	985,000
Tax benefit on non-qualified stock options	1,173,000	383,000
Decrease (increase) in:		
Notes receivable	1,486,000	326,000
Accounts receivable	(1,864,000)	(1,353,000)
Inventories	1,016,000	(4,734,000)
Income tax receivable	482,000	1,447,000
Prepaid expenses and other	(2,317,000)	110,000
Other assets	(6,809,000)	(4,732,000)
Increase (decrease) in:		
Accounts payable	(5,289,000)	(7,952,000)
Accrued liabilities	5,200,000	821,000
Income taxes payable	(16,319,000)	1,336,000
Other	2,172,000	90,000
<b>Net cash provided by operating activities</b>	<b>30,109,000</b>	<b>45,739,000</b>
<b>Cash Flows from Investing Activities:</b>		
Purchases of property and equipment	(9,036,000)	(16,390,000)
Proceeds from sale of property	275,000	989,000
Proceeds from sales of marketable securities	7,423,000	1,489,000
Proceeds from disposition of synthetic DNA business unit	16,087,000	
Purchases of marketable securities	(62,711,000)	(6,000)
Investment in unconsolidated subsidiary	(125,000)	
Purchase of intangibles	(31,846,000)	(2,580,000)
<b>Net cash used in investing activities</b>	<b>(79,933,000)</b>	<b>(16,498,000)</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Table of Contents**QIAGEN N.V.CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(continued)

	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
<b>Cash Flows from Financing Activities:</b>		
Repayment of lines of credit		(972,000)
Proceeds from long-term debt	150,077,000	4,705,000
Repayment of long-term debt	(58,471,000)	(6,293,000)
Proceeds from short-term borrowing		3,221,000
Repayment of short-term borrowing		(3,409,000)
Principal payments on capital leases	(851,000)	(837,000)
Issuance of common shares	3,861,000	1,522,000
<b>Net cash provided by (used in) financing activities</b>	<b>94,616,000</b>	<b>(2,063,000)</b>
Effect of exchange rate changes on cash and cash equivalents	(717,000)	3,190,000
Net increase in cash and cash equivalents	44,075,000	30,368,000
Cash and cash equivalents, beginning of period	98,993,000	44,893,000
<b>Cash and cash equivalents, end of period</b>	<b>\$ 143,068,000</b>	<b>\$ 75,261,000</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.



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QIAGEN N.V.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

I. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements include the accounts of QIAGEN N.V. (the Company), a company incorporated in The Netherlands, and its wholly owned subsidiaries that are not considered variable interest entities. All significant intercompany accounts and transactions have been eliminated. All amounts are presented in U.S. dollars, unless otherwise indicated. Investments in companies where the Company exercises significant influence over the operations, and where the Company is not the primary beneficiary, are accounted for using the equity method. All other investments are accounted for under the cost method.

In the opinion of management and subject to the year-end audit, the accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the Securities and Exchange Commission rules and regulations. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary for a fair presentation have been included. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 20-F for the year ended December 31, 2003.

Stock Based Compensation

At September 30, 2004, the Company has a stock option plan, which is accounted for under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under the plan had an exercise price at least equal to the market value of the underlying common shares on the date of grant. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, an amendment of FASB Statement No. 123 (SFAS No. 148). Had compensation expense for the Company's stock option plan been determined based on the fair value at the grant date, consistent with the methodology prescribed under SFAS No. 148, the Company's net income and earnings per share would have approximated the pro forma amounts indicated below:

**Three months ended  
September 30,**

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	<u>2004</u>	<u>2003</u>
Net income, as reported	\$ 12,640,000	\$ 11,765,000
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(3,788,000)	(2,530,000)
<b>Pro forma net income</b>	<b>\$ 8,852,000</b>	<b>\$ 9,235,000</b>
<b>Earnings per share:</b>		
Basic and Diluted as reported	\$ 0.09	\$ 0.08
Basic and Diluted pro forma	\$ 0.06	\$ 0.06

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	Nine months ended September 30,	
	2004	2003
Net income, as reported	\$ 32,863,000	\$ 33,863,000
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(9,098,000)	(8,800,000)
Pro forma net income	\$ 23,765,000	\$ 25,063,000
Earnings per share:		
Basic and Diluted as reported	\$ 0.22	\$ 0.23
Basic and Diluted pro forma	\$ 0.16	\$ 0.17

**2. Net Income Per Common Share**

Net income per common share for the three and nine months ended September 30, 2004 and 2003 are based on the weighted average number of common shares outstanding and the dilutive effect of stock options outstanding.

The following schedule summarizes the information used to compute net income per common share:

	Three Months Ended September 30,	
	2004	2003
Weighted average number of common shares used to compute basic net income per common share	146,720,000	145,951,000
Dilutive effect of stock options	1,431,000	1,755,000
Weighted average number of common shares used to compute diluted net income per common share	148,151,000	147,706,000
Outstanding stock options having no dilutive effect, not included in above calculation	7,038,000	5,330,000
Outstanding warrants having no dilutive effect, not included in above calculation	11,862,000	
	Nine Months Ended September 30,	
	2004	2003
Weighted average number of common shares used to compute basic net income per common share	146,560,000	145,726,000
Dilutive effect of stock options	1,936,000	1,141,000

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Weighted average number of common shares used to compute diluted net income per common share	148,496,000	146,867,000
Outstanding stock options having no dilutive effect, not included in above calculation	5,559,000	7,123,000
Outstanding warrants having no dilutive effect, not included in above calculation	11,862,000	

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**3. Acquisition**

On September 27, 2004, the Company completed the acquisition of key assets of Molecular Staging, Inc. (MSI) of New Haven, Connecticut. MSI, a privately held company, had developed a range of proprietary products and services based on its Multiple Displacement Amplification (MDA) and Rolling Circle Amplification (RCAT) technology. The key application of MDA is whole genome amplification (WGA) which is designed to eliminate limitations created by the scarce quantities of DNA samples available for customers to perform an increasing number of analyses. The technology portfolio acquired from MSI adds a new dimension of customer benefit and is in the Company's core focus on pre-analytical solutions. The primary reason for the acquisition was to enable the Company to provide customers a solution for the limitations of scarce DNA samples. Following QIAGEN-based nucleic acid purification, WGA provides precise, complete and nearly unlimited copies of the entire genome and thereby creates a sufficient quantity of DNA from even the smallest amounts of starting material enabling a practically unlimited number of analyses. QIAGEN intends to launch a series of kits integrating the newly acquired technology to address specific customer needs in early 2005. MSI's WGA activities will be integrated into the Company's operations in Germantown, Maryland and Hilden, Germany.

Under the terms of the acquisition agreement, QIAGEN acquired the major assets of MSI (which include over 160 patent applications and issued patents) for \$28.5 million in cash. The Company agreed to pay additional potential earn-out amounts of up to \$6.75 million based on revenue milestones in 2004 and 2005. In connection with the acquisition, the Company expensed costs of approximately \$2.1 million, which includes a \$1.5 million charge to cost of sales related to inventory which will be replaced with products integrating the newly acquired technologies and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition. Using the results of an independent appraisal, the purchase price was initially allocated as follows: \$1.2 million to license agreement, \$13.1 million to developed technology (both to be amortized over 14 years), and \$15.6 million to goodwill. As of September 30, 2004, the purchase price allocation associated with this transaction is preliminary and subject to the finalization of the independent valuation report.

**4. Restructuring and Relocation**

In line with the Company's focus of streamlining and strengthening its operations, during the third quarter of 2004 the Company continued plans to realign certain operating functions, primarily in the United States, including the relocation of some of these functions to the Company's North American Headquarters in Germantown, Maryland, which opened in 2002. In the second quarter of 2004 restructuring costs were incurred in connection with the sale of the majority of the Company's synthetic DNA business unit.

In December 2003, the Company began the relocation of certain functions from its subsidiary in Valencia, California to Germantown, Maryland. The Company expensed approximately \$763,000 and \$3.5 million, respectively, of restructuring and relocation costs in the three- and nine-month periods ended September 30, 2004. These costs consisted primarily of relocation and severance costs of \$608,000 and \$2.1 million, lease and facility costs of \$100,000 and \$1.1 million, and other costs of \$55,000 and \$277,000, respectively, in these periods. During the fourth quarter of 2003, the Company expensed costs incurred in connection with these activities of \$5.1 million, consisting of \$798,000 due to employee relocation and severance, \$3.6 million related to inventory write-downs, \$511,000 for investment write-off, and \$190,000 related to lease and facility costs. Additional costs in 2004 are estimated to be approximately \$200,000. These relocation and restructuring efforts were substantially completed in the third quarter of 2004 at a total cost of approximately \$8.6 million.

In June 2004, the Company sold a significant portion of its synthetic DNA business unit to a group of investors, including a former member of management for \$24.3 million, of which \$17.8 million was paid in cash and the remainder is to be paid over a five year period ending in June 2009. The synthetic DNA business unit had operations located in the United States, Germany and Japan. The Company incurred a net loss related to the sale of such business of approximately \$9.8 million, which was included in other miscellaneous expense in the second quarter of 2004. The net loss included net costs of \$4.1 million on the transaction, severance costs of \$2.7 million and lease and facility costs of \$3.0 million.

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During December 2002, the Company decided to close the QIAGEN Genomics site in Bothell, Washington. As a result of the closure and related re-focus of this business, the Company expensed approximately \$10.8 million in the fourth quarter of 2002. Relocation and restructure costs consisted of severance and other costs of \$2.7 million, a non-cash write-off of facilities, equipment and other assets of \$4.7 million and a non-cash write-off of intangible assets, including developed technology and goodwill, of \$3.2 million. Additional costs in the first quarter of 2003 associated with the closure were approximately \$1.6 million, primarily for lease termination. The closure and relocation was completed in the second quarter of 2003.

Activity for accrued restructuring and relocation costs for the nine months ended September 30, 2004 is as follows:

	<b>Accrual Balance 12/31/2003</b>	<b>Amounts Paid in Cash or Settled</b>	<b>2004 Amounts Accrued</b>	<b>Accrual Balance 9/30/2004</b>
Employee relocation or severance and related	\$ 488,000	\$ (2,369,000)	\$ 3,043,000	\$ 1,162,000
Lease and facility	698,000	(494,000)	2,624,000	2,828,000
Inventory	324,000	(319,000)	117,000	122,000
Other	19,000	(173,000)	244,000	90,000
	<b>\$ 1,529,000</b>	<b>\$ (3,355,000)</b>	<b>\$ 6,028,000</b>	<b>\$ 4,202,000</b>

**5. Variable Interest Entities**

In December 2003, the Financial Accounting Standards Board (FASB) issued a revised Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, replacing the original interpretation issued in January 2003. This interpretation requires a company to consolidate a variable interest entity if it is designated as the primary beneficiary of that entity even if the company does not have a majority of voting interests. A variable interest entity is generally defined as an entity where its equity is unable to finance its activities or where the owners of the entity lack the risk and rewards of ownership.

The Company has a 50% interest in a joint venture company, PreAnalytiX GmbH, for which neither joint venture partner is the primary beneficiary within the provisions of FIN 46. Thus, the investment continues to be accounted for under the equity method. QIAGEN AG has been a 50% joint venture partner in PreAnalytiX since November 1999, when the joint venture was formed. PreAnalytiX was formed to develop, manufacture and market integrated systems for the collection, stabilization and purification of nucleic acids for molecular diagnostic testing. At present, the Company's maximum exposure to loss as a result of its involvement with PreAnalytiX is limited to the Company's share of losses from the equity method investment itself. The joint venture entity, PreAnalytiX GmbH, is expected to report net losses at least through the end of 2004.

The Company has a 100% interest in QIAGEN Finance (Luxembourg) S.A. (QIAGEN Finance), a company established for the purpose of issuing the Company's convertible debt. In August 2004, the Company issued \$150.0 million of 1.5% Senior Convertible Notes due in 2024 (the Notes) through QIAGEN Finance, and in turn the proceeds were loaned to subsidiaries within the consolidated QIAGEN N.V. group. QIAGEN N.V. has guaranteed the Notes, and has an agreement with QIAGEN Finance to issue shares to the investors in the event of conversion. According to the provisions of FIN 46, QIAGEN Finance is a variable interest entity with no primary beneficiary, thus is not consolidated. Accordingly, the convertible debt is not included in the consolidated statements of QIAGEN N.V., though QIAGEN N.V. does report the full obligation of the debt through its liabilities to QIAGEN Finance. QIAGEN N.V. accounts for its investment in QIAGEN Finance as an equity investment pursuant to APB No. 18, and accordingly records 100% of the profit or loss of QIAGEN Finance in the loss from equity method

investees.

The Company has concluded that the rest of its equity investments, which are not material to the Company's financial position, do not require consolidation as they are either not variable interest entities or in the event they are variable interest entities, QIAGEN is not considered to be the primary beneficiary.

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The Company has six separate lines of credit amounting to approximately \$11.1 million with variable interest rates, none of which was utilized at September 30, 2004.

At September 30, 2004, long-term debt totaled approximately \$200.4 million, none of which was current. A note payable of EUR 40.0 million, (approximately \$49.7 million at September 30, 2004) which bears interest at a variable rate of EURIBOR plus 0.75 percent is due in June 2011. The loan agreement contains certain financial and non-financial covenants, including but not limited to restrictions on the encumbrance of land, restrictions on the transfer of any patents to third parties and the maintenance of certain financial ratios. The Company was in compliance with these covenants at September 30, 2004.

In August 2004, the Company completed the sale of \$150.0 million principal amount of 1.50% convertible unsubordinated notes due 2024, through its unconsolidated subsidiary QIAGEN Finance. The net proceeds of the Notes were loaned by QIAGEN Finance to consolidated subsidiaries in the U.S. and Switzerland. At September 30, 2004, \$150.8 million is included in long-term debt for the amount of Note proceeds payable to QIAGEN Finance. These long-term notes payable to QIAGEN Finance have a fixed interest rate of 6.5% and are due in August 2011. Interest on the Notes is payable semi-annually in February and August. The Notes were issued at 100% of principal value, and are convertible into 11.9 million shares of common stock at the option of the holder upon the occurrence of certain events at a price of \$12.6449 per share, subject to adjustment. The Notes may be redeemed, in whole or in part, at QIAGEN's option on or after 7 years, at 100% of the principal amount provided the actual trading price of our common stock exceeds 120% of the conversion price for twenty consecutive trading days. In addition, the holders of the Notes may require QIAGEN to repurchase all or a portion of the Notes for 100% of the principal amount, plus accrued interest, on August 18, 2011, 2014 and 2019.

**7. Hedging Contracts**

During the quarter, QIAGEN's German and Swiss subsidiaries entered into forward arrangements which qualify for hedge accounting as cash flow hedges of foreign currency denominated liabilities. At September 30, 2004, these forward contracts totaled \$44.0 million as a hedge to currency risk on intercompany loans. The contracts mature in July 2011. The gain or loss on the change in the fair values of the derivatives are included in earnings to the extent they offset the earnings impact of changes in the fair values of the hedged obligations. Any difference is deferred in accumulated comprehensive income, a component of shareholders' equity. These contracts effectively fix the exchange rate at which the intercompany loans will be settled, so that gains or losses on the forward contracts offset the losses or gains from changes in the value of the underlying intercompany loans.

**8. Inventories**

The components of inventories consist of the following as of September 30, 2004 and December 31, 2003:

	<u>2004</u>	<u>2003</u>
Raw materials	\$ 14,502,000	\$ 15,501,000



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Work in process	21,305,000	21,179,000
Finished goods	21,677,000	28,480,000
	<hr/>	<hr/>
Total inventories	\$ 57,484,000	\$ 65,160,000
	<hr/>	<hr/>

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The following sets forth the intangible assets by major asset class as of September 30, 2004 and December 31, 2003:

	2004		2003	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
<b>Amortized Intangible Assets:</b>				
Patent and license rights	\$ 14,176,000	\$ (5,594,000)	\$ 12,194,000	\$ (4,593,000)
Developed technology	21,177,000	(1,816,000)	8,363,000	(1,443,000)
	<u>\$ 35,353,000</u>	<u>\$ (7,410,000)</u>	<u>\$ 20,557,000</u>	<u>\$ (6,036,000)</u>
<b>Unamortized Intangible Assets:</b>				
Goodwill	<u>\$ 46,887,000</u>		<u>\$ 30,117,000</u>	

The acquisition of Molecular Staging, Inc. on September 27, 2004 resulted in the addition of \$1.2 million to patent and license rights and \$13.1 million to developed technology, which will be amortized over 14 years. The changes in the carrying amount of goodwill for the three months ended September 30, 2004 related to foreign currency translation and the addition of \$15.6 million of goodwill as a result of the acquisition.

Amortization expense on intangible assets totaled approximately \$583,000 and \$1.7 million for the three- and nine-month periods ended September 30, 2004. Amortization of intangibles for the next five years is expected to be approximately:

2005	\$ 3,333,000
2006	\$ 3,089,000
2007	\$ 3,087,000
2008	\$ 2,969,000
2009	\$ 2,571,000

10. Provision for Income Taxes

The provision for income taxes for the three- and nine-month periods ended September 30, 2004 and 2003 is based upon the estimated annualized rate for each of the respective years also considering the estimated tax effect of any transactions.

**Table of Contents**11. Shareholders' Equity

The following tables detail the changes in shareholders' equity from December 31, 2003 to September 30, 2004 and from December 31, 2002 to September 30, 2003, respectively:

	Common Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
	Shares	Amount				
BALANCE AT DECEMBER 31, 2003	146,217,518	\$ 1,485,000	\$ 140,039,000	\$ 163,270,000	\$ 29,992,000	\$ 334,786,000
Net income				32,863,000		32,863,000
Unrealized gain, net on marketable securities					74,000	74,000
Realized gain, net on marketable securities					(523,000)	(523,000)
Unrealized loss, net on hedging contracts					(237,000)	(237,000)
Translation adjustment					(4,764,000)	(4,764,000)
Exercise of stock options	608,931	8,000	3,852,000			3,860,000
Tax benefit in connection with nonqualified stock options			1,173,000			1,173,000
Acceleration of option vesting			295,000			295,000
BALANCE AT SEPTEMBER 30, 2004	146,826,449	\$ 1,493,000	\$ 145,359,000	\$ 196,133,000	\$ 24,542,000	\$ 367,527,000
	Common Shares		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
	Shares	Amount				
Balance at December 31, 2002	145,533,589	\$ 1,478,000	\$ 134,547,000	\$ 120,420,000	\$ 6,586,000	\$ 263,031,000
Net income				33,863,000		33,863,000
Unrealized gain, net on marketable securities					1,259,000	1,259,000
Realized gain, net on marketable securities					(191,000)	(191,000)
Translation adjustment					9,854,000	9,854,000
Exercise of stock options	276,783	3,000	1,519,000			1,522,000
Tax benefit in connection with nonqualified stock options			383,000			383,000
Shares issued in connection with the GenoVision A.S. acquisition	308,421	3,000	2,943,000			2,946,000
BALANCE AT SEPTEMBER 30, 2003	146,118,793	\$ 1,484,000	\$ 139,392,000	\$ 154,283,000	\$ 17,508,000	\$ 312,667,000

**Table of Contents**12. Comprehensive Income

The components of comprehensive income for the three- and nine-month periods ended September 30, 2004 and 2003 are as follows:

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>
Net income	\$ 12,640,000	\$ 11,765,000
Net unrealized gain (loss) on marketable securities	(155,000)	627,000
Net realized (gain) loss on marketable securities	29,000	(191,000)
Net unrealized loss on hedging contracts	(237,000)	
Foreign currency translation adjustments	3,354,000	4,119,000
<b>Comprehensive income</b>	<b>\$ 15,631,000</b>	<b>\$ 16,320,000</b>

  

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>
Net income	\$ 32,863,000	\$ 33,863,000
Net unrealized gain on marketable securities	74,000	1,259,000
Net realized (gain) on marketable securities	(523,000)	(191,000)
Net unrealized loss on hedging contracts	(237,000)	
Foreign currency translation adjustments	(4,764,000)	9,854,000
<b>Comprehensive income</b>	<b>\$ 27,413,000</b>	<b>\$ 44,785,000</b>

The following table is a summary of the components of accumulated other comprehensive income as of September 30, 2004 and December 31, 2003:

	<b>2004</b>	<b>2003</b>
Net unrealized (loss) gain on marketable securities	\$ (352,000)	\$ 96,000
Net unrealized (loss) on hedging contracts	(237,000)	
Foreign currency translation adjustments	25,131,000	29,896,000
<b>Accumulated other comprehensive income</b>	<b>\$ 24,542,000</b>	<b>\$ 29,992,000</b>

13. Stock Options

In the nine-month period ended September 30, 2004, the Company granted options to purchase 2.1 million of the Company's common shares. All options were granted at or above fair market value at the date of grant. As of September 30, 2004, options to purchase 13.6 million common shares were outstanding at exercise prices ranging from \$1.06 to \$49.75.

14. Commitments and Contingencies

From time to time the Company may be party to legal proceedings incidental to its business. As of September 30, 2004, certain claims, suits or complaints arising out of the normal course of business have been filed or were pending against the Company. Although it is not possible to predict the outcome of such litigation, based on the facts known to the Company and after consultation with legal counsel, management believes that such litigation will not have a material adverse effect on its financial position or results of operations.

Pursuant to the purchase agreements for the acquisition of MSI, QIAGEN could be required to make additional contingent cash payments totaling up to \$6.75 million based on revenue milestones in 2004 and 2005. Any contingent payments will be accounted for as additions to the purchase price.

**Table of Contents**15. Supplemental Cash Flow Information

Non-cash investing and financing activities, which are excluded from the consolidated statements of cash flows, along with cash paid for interest and income taxes are as follows:

	Nine Months Ended September 30,	
	2004	2003
<b>Non-cash Investing and Financing Activities:</b>		
<b>Acquisitions:</b>		
Goodwill	\$	\$ 2,946,000
Issuance of common stock	\$	\$ 2,946,000
Forgiveness of government grant	\$	\$ 330,000
Property and equipment purchased through capital leases	\$	\$ 133,000
Note receivable in connection with disposition of assets	\$ 6,352,000	\$
<b>Supplemental Cash Flow Disclosure:</b>		
Cash paid for interest	\$ 2,926,000	\$ 3,581,000
Cash paid for income taxes	\$ 24,075,000	\$ 10,023,000

16. Segment and Related Information

Summarized financial information concerning the Company's reportable segments is shown in the following tables:

	Three Months Ended September 30,	
	2004	2003
<b>Net Sales</b>		
Germany	\$ 40,398,000	\$ 40,322,000
United States	63,928,000	65,415,000
Switzerland	10,198,000	7,378,000
Japan	7,862,000	11,188,000
United Kingdom	7,881,000	6,276,000
Norway	12,000	325,000
Other Countries	12,915,000	12,446,000
The Netherlands	16,000	
Subtotal	143,210,000	143,350,000
Intersegment Elimination	(52,807,000)	(52,904,000)
<b>Total</b>	<b>\$ 90,403,000</b>	<b>\$ 90,446,000</b>

Net Sales	Nine Months Ended	
	September 30,	
	2004	2003
Germany	\$ 122,433,000	\$ 110,682,000
United States	206,556,000	191,670,000
Switzerland	27,591,000	24,050,000
Japan	32,514,000	34,291,000
United Kingdom	24,008,000	18,218,000
Norway	63,000	1,688,000
Other Countries	40,605,000	33,906,000
The Netherlands	47,000	
Subtotal	453,817,000	414,505,000
Intersegment Elimination	(168,719,000)	(158,222,000)
Total	\$ 285,098,000	\$ 256,283,000

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Net sales are attributed to countries based on the location of the Company's subsidiary. QIAGEN operates manufacturing facilities in Germany, Switzerland, Norway and the United States that supply products to other countries. The sales from these manufacturing operations to other countries are included in the Net Sales of such countries in which the manufacturing locations are based. The intercompany portions of such net sales of a reportable segment are excluded through the intersegment elimination to derive consolidated net sales.

<b>Intersegment Sales</b>	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ (22,801,000)	\$ (21,284,000)
United States	(23,423,000)	(25,629,000)
Switzerland	(6,560,000)	(4,178,000)
Japan		(1,449,000)
Norway	(7,000)	(312,000)
Other Countries	(16,000)	(52,000)
<b>Total</b>	<b>\$ (52,807,000)</b>	<b>\$ (52,904,000)</b>

<b>Intersegment Sales</b>	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ (68,684,000)	\$ (60,537,000)
United States	(79,815,000)	(76,410,000)
Switzerland	(17,527,000)	(14,527,000)
Japan	(2,596,000)	(4,948,000)
Norway	(48,000)	(1,572,000)
Other Countries	(49,000)	(228,000)
<b>Total</b>	<b>\$ (168,719,000)</b>	<b>\$ (158,222,000)</b>

All intersegment sales are accounted for by a formula based on local list prices and are eliminated in consolidation.

<b>Operating Income (Loss)</b>	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ 6,838,000	\$ 6,307,000
United States	8,109,000	8,254,000
Switzerland	1,204,000	(150,000)



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Japan	1,355,000	2,098,000
United Kingdom	1,626,000	937,000
Norway	(761,000)	(713,000)
Other Countries	2,265,000	3,091,000
The Netherlands	(863,000)	(1,027,000)
	<hr/>	<hr/>
Subtotal	19,773,000	18,797,000
Intersegment Elimination	1,131,000	513,000
	<hr/>	<hr/>
Total	\$ 20,904,000	\$ 19,310,000
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<b>Operating Income (Loss)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ 18,385,000	\$ 15,490,000
United States	28,999,000	23,871,000
Switzerland	1,806,000	1,155,000
Japan	6,321,000	6,418,000
United Kingdom	4,952,000	3,170,000
Norway	(1,901,000)	(1,733,000)
Other Countries	6,817,000	5,479,000
The Netherlands	(2,785,000)	(2,350,000)
Subtotal	62,594,000	51,500,000
Intersegment Elimination	(709,000)	1,221,000
<b>Total</b>	<b>\$ 61,885,000</b>	<b>\$ 52,721,000</b>

The Netherlands operating loss primarily resulted from general and administrative expenses. The intersegment elimination represents the elimination of intercompany profit.

<b>Assets</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
Germany	\$ 246,279,000	\$ 292,107,000
United States	222,384,000	157,117,000
Switzerland	78,677,000	41,879,000
Japan	24,070,000	36,393,000
United Kingdom	16,190,000	10,929,000
Norway	36,459,000	38,279,000
Other Countries	27,979,000	20,713,000
The Netherlands	199,300,000	180,046,000
Subtotal	851,338,000	777,463,000
Intersegment Elimination	(193,740,000)	(225,533,000)
<b>Total</b>	<b>\$ 657,598,000</b>	<b>\$ 551,930,000</b>

Assets of the Netherlands include cash and cash equivalents, investments, prepaid assets and certain intangibles. The intersegment elimination represents intercompany investments and advances.

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### **OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

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

Our future operating results may be affected by various risk factors, many of which are beyond our control. Certain of the statements included in this report may be forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended, including statements regarding potential future net sales, gross profit, net income and liquidity. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. We caution investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors. Factors which could cause such results to differ materially from those described in the forward-looking statements include those set forth in the risk factors below. As a result, our future development efforts involve a high degree of risk. When considering forward-looking statements, you should keep in mind that the risk factors could cause our actual results to differ significantly from those contained in any forward-looking statement.

#### **Risks Related to Our Business**

##### **An inability to manage our growth or the expansion of our operations could adversely affect our business.**

Our business has grown rapidly, with total net revenues increasing from \$158.2 million in 1999 to \$351.4 million in 2003. In 2002, we opened a research and manufacturing facility in Germantown, Maryland and manufacturing and administration facilities in Germany. The expansion of these facilities added production capacity and increased fixed costs. These higher fixed costs will continue to be a cost of production in the future, and until we more fully utilize the additional capacity of the facilities, our gross profit will be negatively impacted. Additionally we have upgraded our operating and financial systems and expanded the geographic area of our operations, resulting in the hiring of new employees, as well as increased responsibility for both existing and new management personnel. The rapid expansion of our business and addition of new personnel may place a strain on our management and operational systems. Our future operating results will depend on the ability of our management to continue to implement and improve our research, product development, manufacturing, sales and marketing and customer support programs, enhance our operational and financial control systems, expand, train and manage our employee base, and effectively address new issues related to our growth as they arise. There can be no assurance that we will be able to manage our recent or any future expansion successfully, and any inability to do so could have a material adverse effect on our results of operations.

##### **We may not achieve the anticipated benefits of acquisitions of technologies and businesses.**

During the past several years we have acquired a number of companies, through which we have gained access to technologies and products that complement our internally developed product lines. In the future, we may acquire additional technologies, products or businesses to expand our existing and planned business. Acquisitions would expose us to the risks associated with the:

assimilation of new technologies, operations, sites and personnel;

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diversion of resources from our existing business and technologies;

inability to generate revenues to offset associated acquisition costs;

inability to maintain uniform standards, controls, and procedures;

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

issuance of dilutive equity securities;

incurrence or assumption of debt;

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

assumption of liabilities or exposure to claims against acquired entities.

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

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

The market for certain of our products and services is only about fifteen years old. Rapid technological change and frequent new product introductions are typical in this market. Our future success will depend in part on continuous, timely development and introduction of new products that address evolving market requirements. We believe successful new product introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product, and are reluctant to switch thereafter. To the extent that we fail to introduce new and innovative products, we may lose market share to our competitors, which will be difficult or impossible to regain. An inability, for technological or other reasons, to develop successfully and introduce new products could reduce our growth rate or otherwise damage our business. In the past, we have experienced, and are likely to experience in the future, delays in the development and introduction of products. We cannot assure you that we will keep pace with the rapid rate of change in life sciences research, or that our new products will adequately meet the requirements of the marketplace or achieve market acceptance. Some of the factors affecting market acceptance of new products include:

availability, quality and price relative to competitive products;

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

scientists' opinions of the products' utility;

citation of the product in published research; and

general trends in life sciences research.

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

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

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

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

Our success will depend to a large extent on our ability to develop proprietary products and technologies and to establish and protect our patent and trademark rights in these products and technologies. As of December 31, 2003, we owned 50 issued patents in the United States, 39 issued patents in Germany and 243 issued patents in other major industrialized countries. In addition, at December 31, 2003, we had approximately 230 pending patent applications and we intend to file applications for additional patents as our products and technologies are developed. However, the patent positions of technology-based companies, including QIAGEN, involve complex legal and factual questions and may be uncertain, and the laws governing the scope of patent coverage and the periods of enforceability of patent protection are subject to change. In addition, patent applications in the United States are maintained in secrecy until patents issue, and publication of discoveries in the scientific or patent literature tend to lag behind actual discoveries by several months. Therefore, no assurance can be given that patents will issue from any patent applications that we own or license or, if patents do issue, that the claims allowed will be sufficiently broad to protect our technology. In addition, no assurance can be given that any issued patents that we own or license will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide us competitive advantages.

Certain of our products incorporate patents and technologies that are licensed from third parties. These licenses impose various commercialization, sublicensing and other obligations on us. Our failure to comply with these requirements could result in the conversion of the applicable license from being exclusive to non-exclusive in nature or, in some cases, termination of the license.

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

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

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

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

### **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 when incurred. We hedge a portion of the anticipated cash flow that we expect to exchange into other currencies, subject to our short-term financing needs. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effects of exchange rate fluctuations upon future operating results. While we engage in foreign exchange hedging transactions to manage our foreign currency exposure, there can be no assurance that our hedging strategy will adequately protect our operating results from the effects of future exchange rate fluctuations.

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

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

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

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

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

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

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

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

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



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

Our customers within the scientific research markets typically do not keep a significant inventory of QIAGEN products and consequently require overnight delivery of purchases. As such, we heavily rely on air cargo carriers such as DHL, FedEx and 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.

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

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

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

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

Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. We have invested heavily in computerized information systems in order to manage more efficiently the widely dispersed components of our operations. We use SAP as our business information system to integrate most of our North American and European subsidiaries. We have made significant investments in and increased utilization of our SAP system with the opening of our state-of-the-art production and distribution facility in Germantown, Maryland (QIAGEN Sciences, Inc.) and by integrating Xeragon, Inc. and the GenoVision group, which were acquired in 2002. We also integrated systems with third party contract manufacturers via SAP and implemented a module to improve field service operations for our Instruments products. In 2003 we implemented a comprehensive web and security infrastructure including redundant web servers and firewalls to enable internal website hosting. In July 2003 we unveiled our redesigned website with improved navigation and online product ordering. Our E-Shop online ordering system is available in all countries where we have local offices. This system is intended to provide customers with a fast, easy-to-use ordering experience, our online ordering system that is integrated with our back-end ERP system (SAP), reducing manual interaction for our customer service staff. Our system also allows customers to take advantage of design software to design their own custom products, e.g., QuantiTect Assays and siRNA Oligos, and then add them to their online order. The online ordering system for siRNA has gone live in North America and Europe during 2004.

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

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

Effective January 1, 2004 we restructured our management and formed an Executive Committee comprised of QIAGEN's most senior executives responsible for core functions, Dr. Metin Colpan, our former Chief Executive Officer, has transitioned his role to Senior Technology Advisor and has also joined our Supervisory Board. Mr. Peer Schatz, our former Chief Financial Officer, has taken the role of our Chief Executive Officer and Chairman of the Executive Committee. The loss of Mr. Schatz or any of our Executive Committee members could have a material adverse effect on us. Further, although we have not experienced any difficulties attracting or retaining key management and scientific staff, our ability to recruit and retain qualified skilled personnel will also be critical to our success. Due to the intense competition for experienced scientists from numerous pharmaceutical and biotechnology companies and academic and other research institutions, there can be no assurance that we will be able to attract and retain such personnel on acceptable terms. Our planned activities will also require additional personnel, including management, with expertise in areas such as manufacturing and marketing, and the development of such expertise by existing management personnel. The inability to recruit such personnel or develop such expertise could have a material adverse impact on our operations.

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

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

our marketing, sales and customer support efforts;

our research and development activities;

the expansion of our facilities;

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

the demand for our products and services; and

the refinancing of debt.

We currently anticipate that our short-term capital requirements will be satisfied by the results of operations. However, we have outstanding loan facilities at September 30, 2004 of approximately \$200.4 million, \$50.0 million of which we will become due in June 2011, and the balance of which will become due in August 2011. To the extent that our existing resources are insufficient to fund our activities, we may need to raise funds through public or private debt or equity financings. No assurance can be given that such additional funds will be available or, if available, can be obtained on terms acceptable to us. If adequate funds are not available, we may have to reduce expenditures for research and

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development, production or marketing, which could have a material adverse effect on our business. To the extent that additional capital is raised through the sale of equity or convertible securities, the issuance of such securities could result in dilution to our shareholders.

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

We have made and may continue to make strategic investments in complementary businesses as the opportunities arise. We periodically review the carrying value of these investments for impairment, considering factors such as the most recent stock transactions, book values from the most recent financial statements, and forecasts and expectations of the investee. The results of these valuations may fluctuate due to market conditions and other conditions over which we have no control. Estimating the fair value of non-marketable equity investments in life science companies is inherently subjective. If actual events differ from our assumptions and other than temporary unfavorable fluctuations in the valuations of the investments are indicated, it could require a write-down of the investment. This could result in future charges on our earnings that could materially impact our results of operations. It is uncertain whether or not we will realize any long term benefits from these strategic investments.

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

At September 30, 2004, we have a significant amount of debt which carries with it significant debt service obligations. A high level of indebtedness increases the risk that we may default on our debt obligations. We cannot assure you that we will be able to generate sufficient cash flow to pay the interest on our debt or that future working capital, borrowings or equity financing will be available to pay or refinance such debt. If we are unable to generate sufficient cash flow to pay the interest on our debt, we may have to delay or curtail our research and development programs. The level of our indebtedness among other things, could:

make it difficult for us to make payments on the notes;

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

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

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

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

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

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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.

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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.

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 may be subject to extensive regulation by governmental authorities in the United States and other countries and could impact customer demand for our products.

Since the European Union Directive 98/79/EC on in vitro diagnostic medical devices went into effect on December 7, 2003, all products and kits which are used for in vitro diagnostic applications and which are sold after this date have to be compliant with this European directive. In addition to high risk products such as HIV testing systems (list A of Annex II of the directive) or blood glucose testing systems (list B of Annex II of the directive), nucleic acid purification products which are used in diagnostic workflows are affected by this new regulatory framework. The major goals of this directive are to standardize the diagnostic procedures within the European Union, to increase reliability of diagnostic analysis and to enhance patients' safety through the highest level of product safety. These goals are expected to be achieved by the enactment of a large number of mandatory regulations for product development, production, quality control and life cycle surveillance.

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

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

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

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

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

We were incorporated under Dutch law as a public limited liability company and we are organized as a holding company. Currently, our material assets are the outstanding shares of our subsidiaries. We, therefore, are dependent upon payments, dividends and distributions from our subsidiaries for funds to pay our operating and other expenses and to pay future cash dividends or distributions, if any, to holders of our common shares. The lending arrangements entered into by QIAGEN GmbH with a group of banks led by Deutsche Bank in 2001 and amended in July 2004 limits the amount of distributions that can be made by QIAGEN GmbH to QIAGEN N.V. during the period the borrowings are outstanding. The portion of this facility that would otherwise expire in October 2005 was repaid out of new borrowings in the third quarter of 2004. Another portion of this facility will expire in June 2011. Dividends or distributions by subsidiaries to us in a currency other than the U.S. dollar may result in a loss upon a subsequent conversion or disposition of such foreign currency, including a subsequent conversion into U.S. dollars.

### **Risks Related to Our Common Stock**

#### **Our common shares may have a volatile public trading price.**

The market price of the common shares since our initial public offering in September 1996 has increased significantly and been highly volatile. In the past two fiscal years, the closing price of our common shares has ranged from a high of \$20.81 to a low of \$4.51 on the Nasdaq National Market System, and a high of EUR 23.45 to a low of EUR 4.46 on the Frankfurt Stock Exchange. In addition to overall stock market fluctuations, factors which may have a significant impact on the market price of the common shares include:

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

developments in our relationships with collaborative partners;

quarterly variations in our operating results;

changes in government regulations or patent laws;

developments in patent or other proprietary rights;

developments in government spending for life sciences related research; and

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.

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### **Holders of our common shares will not receive dividend income.**

We have not paid cash dividends since our inception and do not anticipate paying any cash dividends on our common shares for the foreseeable future. Although we do not anticipate paying any cash dividends, any cash dividends paid in a currency other than the U.S. dollar will be subject to the risk of foreign currency transaction losses. Investors should not invest in our common shares if they are seeking dividend income; the only return that may be realized through investing in our common shares is through the appreciation in value of such shares.

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

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

### **Future sales of our common shares could adversely affect our stock price.**

Future sales of substantial amounts of our common shares in the public market, or the perception that such sales may occur, could adversely affect the market price of the common shares. As of September 30, 2004, we had outstanding 146,826,449 common shares plus 13,611,297 additional shares subject to outstanding stock options, of which 8,172,000 were exercisable at September 30, 2004. A total of approximately 18.8 million common shares are reserved for issuances under our stock option plan, including those shares subject to outstanding stock options. All of our outstanding common shares are freely saleable except shares held by our affiliates, which are subject to certain limitations on resale. Additionally, holders of Notes issued by QIAGEN Finance are entitled to convert their Notes into approximately 11.9 million common shares, although the resale of these common shares would be subject to some restrictions.



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

Our Articles of Association (the *Articles* ) provide that our shareholders may only suspend or dismiss our managing and supervisory directors against their wishes with a vote of two-thirds of the votes cast representing more than 50 percent of the outstanding shares. They also provide that if the members of our Supervisory Board and our Managing Board have been nominated by the Supervisory Board and Managing Board, shareholders may only overrule this nomination with a vote of two-thirds of the votes cast representing more than 50 percent of the outstanding shares. Certain other provisions of our Articles of Association allow us, under certain circumstances, to prevent a third party from obtaining a majority of the voting control of our shares by issuing preference shares. Pursuant to these provisions (and pursuant to the resolution adopted by our general meeting on July 16, 2004), our Supervisory Board is authorized to issue preference shares or grant rights to subscribe for preference shares if (i) a person has (directly or indirectly) acquired or has expressed a desire to acquire, more than 20 percent of the issued capital of QIAGEN, or (ii) a person holding at least a ten percent interest in our Company has been designated as a hostile person by our Supervisory Board. If the Supervisory Board opposes an intended take-over and authorizes the issuance of preference shares, the bidder may withdraw its bid or enter into negotiations with the Managing Board and /or Supervisory Board and agree on a higher bid price for our shares.

We have also recently granted an option to a Foundation (*Stichting*), subject to the conditions described in the paragraph above, which allows the Foundation to acquire preference shares from us. The option enables the Foundation to acquire such number of preference shares as equals the number of our outstanding common shares less one share. When exercising the option and exercising its voting rights on such shares, the Foundation has to act in our interest and the interests of our stakeholders. The purpose of the Foundation option is to prevent or delay a change of control that would not be in the best interests of us and our stakeholders. See *Description of Share Capital Preference Shares*.

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

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

## **Overview**

We produce and distribute biotechnology products, primarily for the handling, separation and purification of nucleic acids (DNA/RNA), market synthetic nucleic acids and related products and services, as well as license or sell technology or the rights to it. We believe that we are the world's leading provider of innovative enabling technologies and products for nucleic acid handling, separation and purification, based on the nature of our products and technologies and as supported by independent market studies. We operate exclusively in the life sciences industry, and develop, manufacture and market a broad portfolio of proprietary technologies and products to meet the needs of the academic and industrial research markets. Our products enable customers to reliably and rapidly produce high purity nucleic acids without using hazardous reagents or expensive equipment.

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

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On a consolidated basis, operating income increased to \$20.9 million and \$61.9 million in the three- and nine- month periods ended September 30, 2004, compared to \$19.3 million and \$52.7 million in the three- and nine-month periods ending September 30, 2003. The increase in operating income is primarily the result of lower operating costs as a result of our recent restructuring efforts, partially offset by acquisition related costs and costs related to our restructuring and relocation efforts. Further, 2003 operating income includes the results of our former synthetic DNA business unit a significant portion of which was sold at the end of the second quarter in 2004. Accordingly, the three-month period ended September 30, 2004 does not include any sales of synthetic DNA and related products or operating costs related to the former business unit.

On a comparative basis excluding 2003 sales related to the synthetic DNA business unit, sales increased primarily as the result of an increase in our consumables products sales, which experienced a growth rate of 15% in the third quarter of 2004 compared to the third quarter of 2003. During the third quarter of 2004, we continued in our plans to realign certain operating functions in line with our focus to streamline and strengthen our operations. In the three- and nine- month periods ended September 30, 2004, we recorded charges of \$763,000 and \$3.5 million, respectively, related to our restructuring and relocation efforts. On September 27, 2004 we acquired the key assets of MSI and recorded costs related to the acquisition of MSI in the third quarter of 2004 including a \$1.5 million charge to cost of sales for a write-down of inventories, which will be replaced with products integrating newly acquired technologies, and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition. Further, on a comparative basis, operating income during the three- and nine-month periods was negatively impacted by the currency impact of the stronger euro, since a significant portion of our production and operations is based in Germany, along with lower gross margins from instrumentation sales. On June 28, 2004, we sold a significant portion of our synthetic DNA business unit, so our gross margin is no longer negatively impacted by such products and as a result, our reported gross margin for the three-month period ended September 30, 2004 increased to 66% compared to 65% for the same period in 2003.

The following tables set forth summaries of operating income by segment for the three and nine months ended September 30. More complete tables can be found in Note 16 in the accompanying financial statements.

<b>Operating Income</b>	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ 6,838,000	\$ 6,307,000
United States	8,109,000	8,254,000
Switzerland	1,204,000	(150,000)
All other segments	3,622,000	4,386,000
Subtotal	19,773,000	18,797,000
Intersegment Elimination	1,131,000	513,000
<b>Total</b>	<b>\$ 20,904,000</b>	<b>\$ 19,310,000</b>

  

<b>Operating Income</b>	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Germany	\$ 18,385,000	\$ 15,490,000
United States	28,999,000	23,871,000
Switzerland	1,806,000	1,155,000

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All other segments	13,404,000	10,984,000
Subtotal	62,594,000	51,500,000
Intersegment Elimination	(709,000)	1,221,000
Total	\$ 61,885,000	\$ 52,721,000

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

In the three months ended September 30, operating income in the United States in 2004 was essentially unchanged compared to 2003. Operating income in the United States was positively impacted in the third quarter by increased sales of consumables products in 2004 compared to 2003. This increase in sales was partially offset by the lack of sales of synthetic DNA and related products in 2004. Operating expenses in the United States were lower as a result of the recent restructuring efforts. However, the impact of lower operating costs was partially offset by increased acquisition and relocation and restructuring costs.

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

We regularly introduce new products in order to extend the life of our existing product lines as well as to address new market opportunities. During 2003, we introduced over 60 new products. In third quarter of 2004 we launched the worldwide first CE-marked stand alone automated Sample Preparation System for Viral Nucleic Acids composed of the BioRobot MDx DSP; QIAsoft MDxDSP; the QIAamp DSP 96 Virus MDx Protocols and the QIAamp DSP 96 Virus MDx Kit. Further, the declaration of conformity to the IvDD has been obtained for the MDx DSP System which targets diagnostics markets and is approved for such marketing under the CE regime.

**Net Sales**

In the third quarter of 2004, net sales were unchanged at \$90.4 million compared to \$90.4 million in the third quarter of 2003. Net sales in the United States increased to \$40.5 million in 2004 from \$39.8 million in 2003, and net sales outside the United States decreased to \$49.9 million in 2004 from \$50.6 million in 2003.

At the end of the second quarter of 2004 we sold a significant portion of our synthetic DNA business unit. Accordingly, net sales for the third quarter of 2004 did not include any sales of the synthetic DNA products, which were included in the third quarter of 2003. Excluding net sales related to our synthetic DNA business unit, net sales of \$90.4 million in the third quarter of 2004 increased 17% compared to \$77.3 million in the third quarter of 2003. The increase in sales was primarily the result of an increase in our consumables products sales, which experienced a growth rate of 15% in the third quarter of 2004 compared to the third quarter of 2003. Outside of the United States, the increase in net sales was primarily due to strong growth at QIAGEN Ltd., located in the United Kingdom, which reported an increase of 26% (\$1.6 million), and QIAGEN Instruments, located in Switzerland, which reported an increase of 25% (\$416,000). QIAGEN Benelux B.V., our newly established sales subsidiary serving Belgium, The Netherlands and Luxembourg regions, reported sales of \$1.7 million during the third quarter. Prior to the establishment of this new subsidiary, QIAGEN GmbH reported sales to the Benelux region. During the third quarter, QIAGEN K.K., located in Japan, reported a decrease of 19% (\$1.9 million), which is primarily due to the sale a significant portion of the DNA business unit in the second quarter of 2004. Excluding Japan's 2003 sales related to the synthetic DNA business unit, QIAGEN K.K.'s net sales increased 7% which, as a percentage of sales, has improved over the previous quarter, but is still lower than reported in previous periods and is attributable to a change in local purchasing procedures during the quarter. We believe the impact of this change is temporary.

For the nine months ended September 30, 2004, net sales increased 11% to \$285.1 million from \$256.3 million in the same period of 2003. Net sales in the United States increased to \$126.7 million in 2004 from \$115.3 million in 2003, and net sales outside the United States increased to \$158.4 million in 2004 from \$141.0 million in 2003. Outside of the United States, net sales continued to be favorably affected by growth at QIAGEN GmbH and QIAGEN Ltd., which reported increases of 8% (or \$4.1 million) and 32% (or \$5.8 million), respectively for the nine

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months ended September 30, 2004 compared to the comparable period of 2003.

Changes in exchange rates continued to affect the growth rate of net sales for the quarter ended September 30, 2004. A significant portion of our revenues is denominated in European Union euros. Using identical foreign exchange rates for both periods, net sales outside of the United States decreased approximately 5% and increased 5% as compared to the reported increase of 0% and 11% for the three-month and nine-month periods ended September 30, 2004, respectively. See Currency Fluctuations.

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### **Gross Profit**

Gross profit was \$59.7 million or 66% of net sales in the quarter ended September 30, 2004 as compared to \$59.1 million or 65% of net sales for the same period in 2003. For the year ended December 31, 2003, gross profit was 65% as a percentage of net sales. The 2003 gross profit includes sales of our synthetic DNA business unit a significant portion of which was sold at the end of the second quarter in 2004. Accordingly, the three-month period ended September 30, 2004 does not include any sales of synthetic DNA and related products, which carried a lower gross profit than our consumables products, thus the reported gross profit in the third quarter of 2004 is higher than compared to the same period in 2003. Further, the increase in gross profit as a percentage of net sales is also attributable to the increase in net sales of consumable products, partially offset by the currency impact of the stronger euro. Additionally, manufacturing costs incurred at our newer production facilities in Germantown, Maryland and Hilden, Germany, which began production operations in the second and fourth quarters of 2002, respectively, negatively impacted gross profit. These facilities added production capacity, which resulted in increased fixed production costs. These higher fixed costs will continue to be a cost of production in the future, though as production increases and we more fully utilize the additional capacity of these facilities, we expect that gross profit, as a percentage of sales, will increase. In the third quarter of 2004, in connection with the acquisition of Molecular Staging, Inc. we expensed \$1.5 million of inventory to cost of sales, which will be replaced with products integrating the newly acquired technologies.

Gross profit for the nine-month period ended September 30, 2004 was \$189.3 million or 66% of net sales as compared to \$169.2 million or 66% of net sales for the same period in 2003.

### **Research and Development**

Research and development expenses increased 1% to \$7.6 million (8% of net sales) in the third quarter of 2004 compared with \$7.5 million (8% of net sales) in the same period of 2003. Using identical foreign exchange rates for both quarters, research and development expenses decreased approximately 6%. We expanded our German research facility late in 2002, which resulted in increased costs related to research and development starting in the first quarter of 2003. Our U.S. facility located in Germantown, Maryland now includes limited research and development activities, including those related to siRNA. The increase in research and development expenses is also attributable to the currency impact of the stronger euro, and was partially offset by the sale of our former synthetic DNA business unit in the second quarter of 2004. As we continue to expand our research activities and product development capabilities, additional expense will be incurred related to research and development facility costs and the employees engaged in our research and development efforts. We have a strong commitment to research and development and anticipate that absolute research and development expenses may increase significantly.

For the nine-month period ended September 30, 2004, research and development expenses increased 16% to \$26.3 million (9% of net sales) compared to \$22.7 million (9% of net sales) for the same period in 2003.

### **Sales and Marketing**

Sales and marketing expenses decreased 4% to \$20.0 million (22% of net sales) in the third quarter of 2004 from \$20.8 million (23% of net sales) in the same period of 2003. Using identical foreign exchange rates for both quarters, sales and marketing expenses decreased 8%. Sales and marketing costs are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses and other promotional items. The decrease in sales and marketing expenses in the third quarter of 2004 is a result of our recent restructuring and relocation efforts. We anticipate that sales and marketing costs may increase along with new product introductions and continued growth in sales of our products.

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Sales and marketing expenses increased 7% to \$65.0 million (23% of net sales) in the nine-month period ended September 30, 2004 from \$60.6 million (24% of net sales) in the comparable period of 2003.



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### **General and Administrative**

General and administrative expenses decreased 14% to \$9.8 million (11% of net sales) in the third quarter of 2004 from \$11.4 million (13% of net sales) in the same period of 2003. Using identical foreign exchange rates for both quarters, general and administrative expenses decreased approximately 18%. General and administrative expenses primarily represent the costs required to support our administrative infrastructure which, until our recent restructuring, continued to expand along with our growth. General and administrative expenses were lower in the third quarter of 2004 as a result of our relocation and restructuring efforts, including the sale of our synthetic DNA business unit, which we sold at the end of June 2004.

For the nine-month period ended September 30, 2004, general and administrative expenses increased 1% to \$32.0 million (11% of net sales) from \$31.6 million (12% of net sales) in the same period 2003.

### **Acquisition and Related Costs**

Costs related to the acquisition of MSI in the third quarter of 2004 included a \$1.5 million charge to cost of sales for a write-down of inventories, which will be replaced with products integrating newly acquired technologies, and a \$572,000 charge to operating expenses related to the impairment of other assets as a result of the acquisition.

### **Restructuring and Relocation Costs**

In line with our focus to streamline and strengthen our operations, during the third quarter of 2004 we continued in our plans to realign certain operating functions. In December 2003, we began the relocation of certain functions from our subsidiary in Valencia, California to our North American Headquarters located in Germantown, Maryland. During the third quarter of 2004, we recognized approximately \$763,000 in operating expenses related to employee relocation and severance costs. We expect to incur an estimated additional \$200,000 in one-time costs in the remainder of 2004. These restructuring and relocation activities, which include \$5.1 million of costs in the fourth quarter of 2003, are expected to be completed by the end of 2004 for a total cost of approximately \$8.8 million.

At the end of 2002, we closed our QIAGEN Genomics site in Bothell, Washington. The closure has contributed to our profitability as a result of lower operating costs. We had expenses of approximately \$1.6 million in the first quarter of 2003 related to the closure, consisting primarily of lease and facility costs.

### **Other Income (Expense)**

Other expense was \$577,000 in the third quarter of 2004 compared to other expense of \$287,000 in the third quarter of 2003. This increase in expense was mainly due to lower research and development grant income, increased interest expense and miscellaneous income, and a higher loss from equity method investee, partially offset by higher interest income and gains on foreign currency transactions.

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In the three months ended September 30, 2004, research and development grant income from European as well as German state and federal government grants decreased to \$296,000 from \$984,000 in the same period of 2003. We conduct significant research and development activities in Germany, and expect to continue to apply for such research and development grants in the future.

Interest expense increased to \$1.7 million in the third quarter of 2004 compared to \$972,000 in the same period of 2003. Interest costs relate primarily to our long-term borrowings of the proceeds from the convertible debt offering along with the long-term debt related to our facility construction.

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Other miscellaneous income increased to \$616,000 in the third quarter of 2004 compared to \$63,000 in the third quarter of 2003 primarily as the result of a gain on the disposition of fixed assets.

In the three-month period ended September 30, 2004, we recorded a net loss from an equity method investee of \$753,000 compared to \$597,000 in the same period of 2003. The loss primarily represents our share of losses from our equity investment in PreAnalytiX. We sell certain products directly as joint venture products and certain products are sold via protocols. The joint venture entity itself, PreAnalytiX GmbH, is expected to report net losses for our fiscal year 2004. As previously disclosed, we intend to continue to make strategic investments in complementary businesses as the opportunities arise. Accordingly, we may continue to record losses on equity investments in start-up companies based on our ownership interest in such companies.

For the quarter ended September 30, 2004, interest income increased to \$861,000 from \$227,000 in the same period of 2003. Interest income is derived mainly from interest bearing cash accounts and investments, and from our investment of funds in investment grade, interest-bearing marketable securities. As of September 30, 2004, we had approximately \$62.4 million invested in such securities. The weighted average interest rates on the marketable securities portfolio was 1.67% in the third quarter of 2004, compared to 1.26% to 1.35% in the third quarter of 2003.

We recorded a gain from foreign currency transactions of \$56,000 in the third quarter of 2004 as compared to a gain of \$8,000 in the third quarter of 2003. The gain from foreign currency transactions reflects net effects from conducting business in currencies other than the U.S. dollar. QIAGEN N.V.'s functional currency is the U.S. dollar and our subsidiaries' functional currencies are the European Union euro, the British pound, the Swiss franc, the Norwegian krone, the U.S. dollar, the Australian dollar, the Canadian dollar, and the Japanese yen. See [Currency Fluctuations](#) .

Other expense was \$8.8 million in the nine month period ended September 30, 2004 compared to other income of \$59,000 in the comparable period of 2003. This increase in expense was primarily due to the sale of the majority of our synthetic DNA business unit to a group of investors including a former member of management. As a result we recorded a net loss related to the sale of \$9.8 million in the second quarter of 2004.

## **Provision for Income Taxes**

Our effective tax rate remained unchanged at 38% in the third quarter of 2004 compared to 38% in the third quarter of 2003. Our operating subsidiaries are exposed to effective tax rates ranging from approximately 25% to approximately 42%. Fluctuation in the distribution of pre-tax income among these entities can lead to fluctuations of the effective tax rate in our consolidated financial statements.

## **Liquidity and Capital Resources**

To date, we have funded our business primarily through internally generated funds, debt and the private and public sales of equity. As of September 30, 2004 and December 31, 2003, we had cash and cash equivalents of \$143.1 million and \$99.0 million, respectively, and investments in current marketable securities of \$62.4 million and \$7.0 million, respectively. Cash and cash equivalents are primarily held in U.S. dollars, other than those cash balances maintained in the local currencies of our subsidiaries to meet local working capital needs. The increase in cash and cash equivalents from December 31, 2003 to September 30, 2004 was primarily due to cash provided by operations of \$30.1 million and cash provided by financing activities of \$94.6 million, partially offset by cash used in investing activities of \$80.0 million. Current marketable securities consist of investments in high-grade corporate securities. As of September 30, 2004 and December 31, 2003, we had

working capital of \$287.1 million and \$163.6 million, respectively.

For the nine-month periods ended September 30, 2004 and 2003, we generated net cash from operating activities of \$30.1 million and \$45.7 million, respectively. Cash provided by operating activities decreased in the nine months ended September 30, 2004 compared to the same period in 2003 primarily due to decreases in deferred taxes, accounts payable and taxes payable, partially offset by a loss on the disposition of a significant portion of our synthetic DNA business unit, a decrease in inventories, and an increases in accrued liabilities. Since we rely heavily on cash generated from operating activities to fund our business, a decrease in demand for our products or significant technological advances of competitors would have a negative impact on our liquidity.

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Approximately \$80.0 million of cash was used in investing activities during the first nine months of 2004, compared to \$16.5 million for the same period of 2003. Investing activities during 2004 consisted principally of the purchase of intangible assets in connection with our acquisition of MSI, proceeds from the disposition of a portion of our synthetic DNA business unit and the purchases of marketable securities along with the purchases of property and equipment in connection with our operations in the U.S. and Germany. At the end of 2002, we had completed the expansion of our production operation facilities in the U.S. and Germany, and during the first quarter of 2003, had continued to make capital investments related to the new facilities.

Financing activities provided \$94.6 million in cash during the third quarter of 2004, compared to cash used of \$2.1 million in the same period of 2003. Cash provided during the quarter was primarily due to the long-term borrowings of the convertible debt proceeds and the issuance of common shares as a result of stock option exercises, partially offset by the repayment of long-term debt and capital lease payments.

We have credit lines totaling \$11.1 million at variable interest rates, none of which was utilized as of September 30, 2004. We also have capital lease obligations in the amount of \$14.0 million. In addition at September 30, 2004, we had \$200.4 million of long-term debt that consists of three notes payable.

Two of the notes payable are the long-term borrowings of the proceeds from our issuance of \$150.0 million senior unsubordinated convertible notes, with a 1.5% coupon due in 2024 through an unconsolidated subsidiary, QIAGEN Finance (Luxembourg) S.A., which was established for this purpose. The net proceeds were loaned by QIAGEN Finance to our consolidated U.S. and Swiss subsidiaries. The long-term notes payable to QIAGEN Finance have a fixed rate of 6.5% and are due in August 2011. The convertible notes issued by QIAGEN Finance are convertible into shares of our common stock at a conversion price of \$12.6449 subject to adjustment. Approximately \$58.0 million of the proceeds was used to repay long-term debt at higher interest rates and approximately \$29.5 million was used to finance the acquisition of MSI. We intend to use the remaining net proceeds for general corporate purposes. The third note is a note payable of EUR 40.0 million, (approximately \$49.7 million at September 30, 2004) which bears interest at a variable interest rate of EURIBOR plus 0.75 percent is due in June 2011.

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

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### **Quantitative and Qualitative Disclosures About Market Risk**

Our market risk relates primarily to interest rate exposures on cash, marketable securities and borrowings and foreign currency exposures on intercompany transactions. The overall objective of our risk management is to reduce the potential negative earnings effects from changes in interest and foreign exchange rates. Exposures are managed through operational methods and financial instruments. We do not use financial instruments for trading or other speculative purposes.

#### **Interest Rate Risk**

Interest income earned on our investment portfolio is affected by changes in the relative levels of market interest rates. We only invest in high-grade investment securities. For the quarter ended September 30, 2004, the weighted average interest rate on our marketable securities portfolio was 1.67%.

Borrowings against lines of credit are at variable interest rates. At September 30, 2004, and December 31, 2003, we did not have any amounts outstanding under our lines of credit. A hypothetical adverse 10% movement in market interest rates would not have materially impacted our financial statements.

At September 30, 2004, we had \$200.4 million in long-term debt, of which \$49.7 million was at a variable rate. A hypothetical adverse 10% movement in market interest rates would decrease 2004 quarter-to-date and year-to-date earnings by approximately \$35,000 and \$105,000, respectively, based on the quarter-end interest rate, a loan balance consistent with that at quarter-end and a constant foreign exchange rate.

#### **Currency Fluctuations**

We operate on an international basis. A significant portion of our revenues and expenses are earned and incurred in currencies other than the U.S. dollar. The euro is the most significant such currency, with others including the British pound, Japanese yen, Swiss franc, Norwegian krone and Canadian and Australian dollars. Fluctuations in the value of the currencies in which we conduct our business relative to the U.S. dollar have caused and will continue to cause U.S. dollar translations of such currencies to vary from one period to another. Due to the number of currencies involved, the constantly changing currency exposures, and the potential substantial volatility of currency exchange rates, we cannot predict the effect of exchange rate fluctuations upon future operating results. However, because we have substantial expenses as well as revenues in each of our principal functional currencies, the exposure of our financial results to currency fluctuations is reduced. In general terms, depreciation of the U.S. dollar against our other foreign currencies, such as occurred in 2003 with respect to the euro, will increase reported net sales. However, this impact normally will be at least partially offset in the results of operations by gains or losses from foreign currency transactions.

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### **Currency Hedging**

In the ordinary course of business, we purchase instruments with which we intend to hedge foreign currency fluctuations with the principal objective of minimizing the risks and/or costs associated with global financial and operating activities. Generally, we hedge a majority of the anticipated cash flow that we expect to exchange into other currencies, subject to our short-term financing needs. We do not utilize financial instruments for trading or other speculative purposes.

At September 30, 2004, these foreign currency instruments consisted of options, which give us the right, but not the obligation, to purchase foreign currencies in exchange for U.S. dollars at predetermined exchange rates. These options are marked to market through our statements of income and are not designated as effective hedges according to the provisions of SFAS 133. At September 30, 2004, we held two foreign currency exchange options, one totaling \$1.0 million, which had a notional exchange rate of EUR/USD 1.22 and expired the end of October 2004. The second totals \$1.0 million, has an interest rate of EUR/USD 1.23 and expires the end of November 2004.

During the quarter, our German and Swiss subsidiaries entered into forward arrangements which qualify for hedge accounting as cash flow hedges of foreign currency denominated liabilities. At September 30, 2004, these forward contracts totaled \$44.0 million as a hedge to currency risk on intercompany loans. The contracts mature in July 2011. The gain or loss on the change in the fair values of the derivatives are included in earnings to the extent they offset the earnings impact of changes in the fair values of the hedged obligations. Any difference is deferred in accumulated comprehensive income, a component of shareholders' equity. These contracts effectively fix the exchange rate at which the intercompany loans will be settled in, so that gains or losses on the forward contracts offset the losses or gains from changes in the value of the underlying intercompany loans.

### **Foreign Currency Exchange Rate Risk**

We have production and manufacturing facilities located in Germany and Switzerland, and intercompany sales of inventory expose us to foreign currency exchange rate risk. Intercompany sales of inventory are generally denominated in the local currency of the subsidiary purchasing the inventory in order to centralize foreign currency risk with the manufacturing subsidiary. Payment for intercompany purchases of inventory is required within 30 days from invoice date. The delay between the date the manufacturing subsidiaries record revenue and the date when the payment is received from the purchasing subsidiaries exposes us to foreign exchange risk. The exposure results primarily from those transactions between the manufacturing subsidiaries and the U.S.

The foreign currency exchange rate risk is partially offset by transactions of the manufacturing subsidiary denominated in U.S. dollars. Hedging instruments include foreign currency put options that are purchased to protect the majority of the existing and/or anticipated receivables resulting from intercompany sales from the manufacturing subsidiary to the U.S. These options give us the right, but not the obligation, to purchase foreign currencies in exchange for U.S. dollars at predetermined exchange rates. Management does not believe that our exposure to foreign currency exchange rate risk is material.

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### **Application of Critical Accounting Policies**

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

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

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

**Investments.** We have equity investments accounted for under the cost method. We periodically review the carrying value of these investments for permanent impairment, considering factors such as the most recent stock transactions, book values from the most recent financial statements, and forecasts and expectations of the investee. Estimating the fair value of these non-marketable equity investments in life science companies is inherently subjective, and if actual events differ from management's assumptions, it could require a write-down of the investment that could materially impact our financial position and results of operations.

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

**Goodwill and Other Intangible Assets.** We account for acquisitions under the purchase method of accounting, typically resulting in goodwill. Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, requires us to assess goodwill for impairment at least annually in the absence of an indicator of possible impairment and immediately upon an indicator of possible impairment. The statement requires estimates of the fair value of our reporting units. If we determine that the fair values are less than the carrying amount of goodwill recorded, we must recognize an impairment in our financial statements. Due to the numerous variables associated with our judgments



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

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

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

## **Authoritative Pronouncements**

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



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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

QIAGEN N.V.

By:

/s/ Roland Sackers

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Roland Sackers  
Chief Financial Officer

Date: November 15, 2004