

# Annual Report 2012

Making  
improvements in  
life possible



Sample & Assay Technologies

## OUR MISSION

As the innovative market and technology leader, QIAGEN creates Sample & Assay Technologies that enable access to valuable molecular information from any biological sample.

Our mission is to enable our customers to achieve outstanding success and breakthroughs in life sciences, applied testing, pharma and molecular diagnostics. We thereby make improvements in life possible.

Our commitment to the markets, customers and patients we serve drives our innovation and leadership in all areas where our Sample & Assay Technologies are required.

The exceptional talent, skill and passion of our employees are key to QIAGEN's excellence, success and value.

# KEY FIGURES

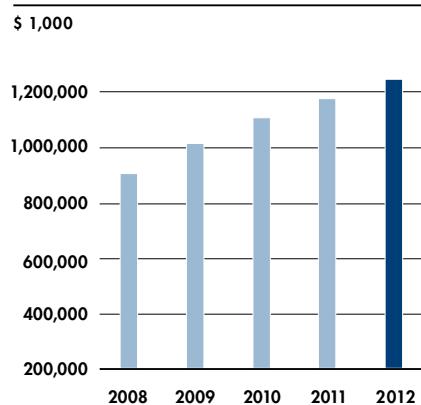
## QIAGEN Key Figures 2012

As of December 31

\$ 1,000 except per share data	2012	2011	2010	2009	2008
<b>Results</b>					
Net sales	1,254,456	1,169,747	1,087,431	1,009,825	892,975
Operating income	169,814	99,588	188,537	180,205	145,662
Net income <sup>1</sup>	129,506	96,038	144,311	137,767	89,033
Basic earnings per share <sup>1</sup>	0.55	0.41	0.62	0.67	0.45
Diluted earnings per share (EPS) <sup>1</sup>	0.54	0.40	0.60	0.64	0.44
<b>Number of shares (in thousands)</b>					
Weighted average number of common shares used to compute basic net income per common share	235,582	233,850	232,635	206,928	196,804
Weighted average number of common shares used to compute diluted net income per common share	240,746	239,064	240,483	213,612	204,259
<b>Cash flow</b>					
Cash flow from operations	244,880	244,779	250,752	216,995	172,998
Capital expenditures for property, plant and equipment	101,996	86,805	79,666	52,179	39,448
Free cash flow					
(cash flow from operations less capital expenditures)	142,884	157,974	171,085	164,816	133,550
Cash EPS					
(cash flow from operations / weighted average number of diluted shares)	1.02	1.02	1.04	1.02	0.85
<b>Balance sheet</b>					
Total assets	4,087,631	3,729,685	3,878,478	3,769,219	2,810,789
Cash and cash equivalents	394,037	221,133	828,407	825,557	333,313
Total long-term liabilities, including current portion	1,101,550	725,874	1,118,932	1,171,065	1,128,301
Total shareholders' equity <sup>1</sup>	2,724,363	2,557,798	2,476,353	2,291,169	1,453,844

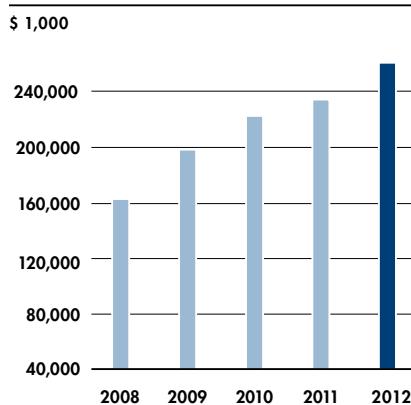
<sup>1</sup>Attributable to the owners of QIAGEN N.V.

### Net Sales



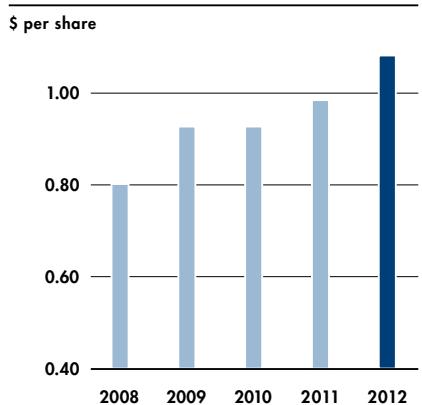
### Adjusted Net Income

Excluding acquisition, business integration, restructuring and related charges as well as amortization of acquired IP and equity-based compensation of \$74.3 million in 2008, \$61.8 million in 2009, \$78.4 million in 2010, \$138.4 million in 2011, and \$131.2 million in 2012.



### Adjusted Diluted Earnings per Share

Excluding acquisition, business integration, restructuring and related charges as well as amortization of acquired IP and equity-based compensation of \$0.36 in 2008, \$0.29 in 2009, \$0.33 in 2010, \$0.58 in 2011, and \$0.54 in 2012.



5-year CAGR → +14%

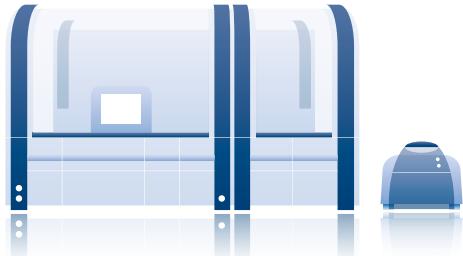
5-year CAGR → +19%

5-year CAGR → +11%

CAGR – Compound annual growth rate

# QIAGEN AT A GLANCE

## Product Categories



14%

### Instruments

are used with consumables, enabling customers to fully automate processes from the preparation of clinical samples to delivery of valuable results.



86%

### Consumable products

are specialized kits that contain all necessary materials to support the use of sample and/or assay technologies.

## Customer Classes

Percentage share of 2012 net sales



### Molecular Diagnostics

Physicians, hospitals and healthcare providers use QIAGEN technologies to save lives and fight disease. Our products support disease prevention such as screening women for risk of cervical cancer; profiling of patients to pinpoint many diseases; personalized healthcare to guide treatment decisions; and point of need testing to provide on-site diagnosis.

### Applied Testing

Professionals in fields such as human identification and forensics, food testing and veterinary medicine use QIAGEN technologies in commercial applications beyond human healthcare. Our products are helping to solve crimes, secure food supplies and detect potentially devastating livestock diseases.

### Pharma

Scientists in the pharmaceutical and biotechnology industries look to QIAGEN to advance gene-based drug discovery and development, supporting the creation of new medical breakthroughs.

### Academia

Researchers at life science laboratories around the world depend on QIAGEN to advance our understanding of the molecular basis of life. Customers include universities and research institutes.

At the forefront of the molecular biology revolution, more than 500,000 customers worldwide are using QIAGEN Sample & Assay Technologies to achieve breakthroughs based on the building blocks of life – DNA, RNA and proteins.

Doctors are diagnosing diseases more precisely and quickly to guide treatment decisions. Scientists are conquering new frontiers in the understanding of life – and translating that knowledge into better medications. And experts are safeguarding the public with molecular technologies for human identification, veterinary testing and food safety.

A new generation of QIAGEN innovation is creating value in the global market with solutions not even imagined a few years ago. And so we are fulfilling our mission of making improvements in life possible.



# Improving healthcare

Innovative molecular diagnostics from QIAGEN provide precise, reliable answers to guide medical treatments and advance the fight against disease.



At the Queen Elizabeth Hospital Birmingham, oncologists and pathologists work hand in hand to break the code of cancer and find the right treatment for patients.

A close-up photograph showing a cow's udder being milked by a mechanical milking machine. The machine's dark, curved metal components are visible against the light-colored skin of the cow's teats. The background is blurred, focusing attention on the milking process.

Given the vulnerability of our food supplies, modern monitoring and surveillance systems need to span the entire value chain from farm to fork.

# Ensuring safety

In applied settings in laboratories and in the field, QIAGEN's technologies are helping to protect the public by solving crimes and safeguarding the food processing chain.

# Creating new medicines

QIAGEN's vast gene and disease pathway library – and efficient workflows for pharmaceutical R&D – are transforming the development of new treatments.





Collaborations with partners such as the Shanghai Clinical Research Center, using biomarkers and molecular technologies, increasingly drive the success of pharmaceutical R&D.

A close-up photograph of a man with short brown hair and glasses, wearing a light-colored lab coat over a dark shirt. He is looking intently at a computer monitor in front of him. In the background, there are shelves filled with red and white binders or files. A blue rectangular box is overlaid on the right side of the image, containing text.

Molecular technologies help scientists at the New Jersey Medical School understand the dissemination of dangerous pathogens such as tuberculosis.

# Advancing science

QIAGEN's automated workflows and broad array of molecular test content are enabling academic scientists to challenge new frontiers.



# Accelerating innovation and growth

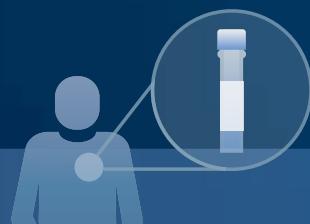
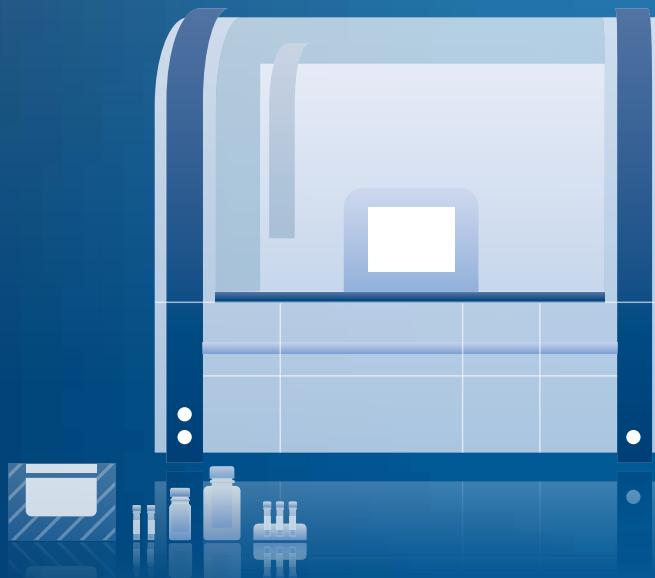


Molecular Diagnostics

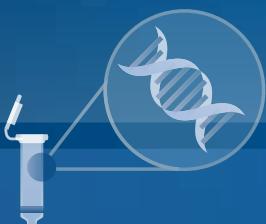


Applied Testing

QIAGEN has an industry leading portfolio of Sample & Assay Technologies addressing the needs of more than 500,000 customers worldwide.



Biological Sample



Sample Technologies

- Global leadership
- Attractive and expanding markets
- Track record of innovation
- Diverse growth opportunities



Pharma



Academia



Assay Technologies

Valuable Molecular Information

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Translating knowledge into medicines

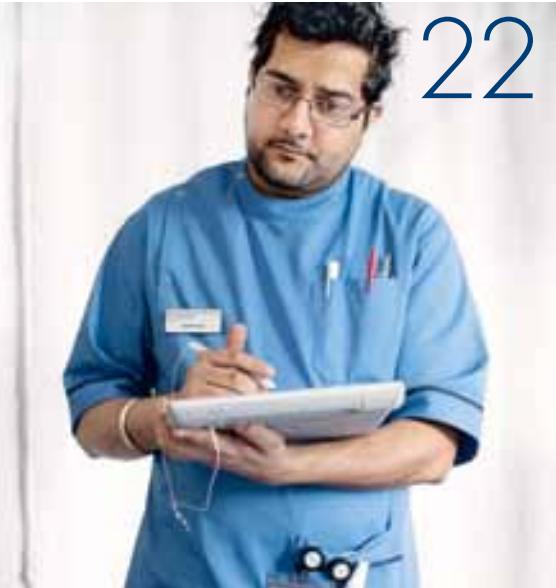
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PEER M. SCHATZ  
Chief Executive Officer

## Dear Shareholders

People are achieving truly amazing things these days in terms of translating knowledge about the building blocks of life – DNA, RNA and proteins – into practical applications that are making improvements in life. Doctors are helping patients by battling diseases in more precise and effective ways. Scientists are advancing the frontiers of biology at an unprecedented speed. Farmers and food companies are using molecular tests to ensure the safety and authenticity of what we eat. Police are unraveling mysteries of various crimes that would never have been solved before. And scientists are creating innovative medications that provide new hope to patients.

The people who are creating and applying these breakthroughs are among our customers.

Around the world, QIAGEN's customers are using our Sample & Assay Technologies to do things that were not possible, in some cases not even imaginable, a few years ago. QIAGEN is at the center of the ongoing revolution in molecular biology. And our 4,000 employees are focused on our mission to provide solutions that help our customers – doctors, food producers, investigators, scientists and others – to make improvements in life possible.

### **Delivering improving performance**

In 2012 we delivered on our goal of accelerating sales and earnings growth. Net sales rose 10% at constant exchange rates to reach \$1.25 billion. Even amid challenging macroeconomic conditions, QIAGEN's sales

grew across all geographic regions and customer classes. We also delivered earnings ahead of our targets in 2012, with net income attributable to the owners of QIAGEN N.V. rising 35% to \$ 129.5 million. We have focused our organization on a group of strategic growth drivers, reallocating resources to support these initiatives while also improving profitability. Results on an adjusted basis, which exclude costs such as restructuring-related charges as well as the amortization of intangible assets and share-based compensation, also showed sustained improvement over 2011.

In 2013 and beyond, we expect to further accelerate sales and adjusted earnings growth. As we set important milestones for QIAGEN's growth, we are taking action throughout the organization to improve efficiency and effectiveness, and we are encouraged by the progress to date.

#### **Exceeding customer expectations**

QIAGEN has built a significant competitive advantage by cultivating customer relationships through the entire value chain of Sample & Assay Technologies – from basic research for the life sciences, to drug development and clinical trials, to applications in industry and public service, to advanced diagnostics for healthcare providers. We strive to have best-in-class knowledge of the workflow and content needs of our customers, and focus on exceeding their expectations.

In **Molecular Diagnostics**, which grew to represent 49% of net sales in 2012, we continue to create new products to help improve disease prevention and treatment. We also are transforming workflows to create value for laboratories, particularly with our QIAasympo ny automation platform. Net sales in Molecular Diagnostics grew 15% at constant exchange rates (CER) in 2012.

Sales of our solutions in Personalized Healthcare grew at a double-digit rate on global demand for our *therascreen* companion diagnostics and revenues from co-development projects with leading pharmaceutical companies, and surpassed \$ 100 million in sales for the first time in 2012. Following mid-year FDA approval of the *therascreen KRAS RGQ PCR Kit* for use in metastatic colorectal cancer patients, conversion of the U.S. market from lab-developed tests to our FDA-approved test has progressed at a rapid pace. In 2012 we also launched the *therascreen BRAF* companion diagnostic in Europe, and we are preparing for a potential U.S. launch of the *therascreen EGFR* test in non-small cell lung cancer patients in 2013.

In Prevention, the QuantiFERON-TB test (acquired with Cellestis in 2011) has become a new growth driver through initiatives to drive greater use of this new "gold standard" for detection of latent tuberculosis (TB) in the U.S. and Europe, a condition estimated to affect about 1 in 3 people worldwide. We are successfully maintaining our market leadership in screening tests for human papillomavirus (HPV), for prevention of cervical cancer, as slightly higher volumes were more than offset by price pressures from competition in the U.S. market.

Our Profiling franchise is rapidly expanding as customers choose to implement the QIAasympo ny automation platform as their system of choice for efficient processing of assays for use in identifying and evaluating various viral diseases in transplant cases and other areas. A key achievement was the U.S. regulatory clearance in 2012 of the Rotor-Gene Q MDx instrument (a real-time PCR platform) in the QIAasympo ny family.

In Point of Need, the AmniSure assay for premature rupture of fetal membranes in pregnant women has become an important growth driver since its acquisition in May 2012, and is expected to contribute strong growth. Our portable ESEQuant Lateral Flow System gained its first regulatory approval in healthcare, from China's State Food and Drug Administration. In partnership with a Chinese firm, the platform will be used to diagnose heart attacks in emergency room settings. Overall, our Point of Need franchise generated approximately \$ 40 million of sales in 2012.

**Applied Testing** customers are increasingly turning to the QIAsymphony automation platform and QIAGEN consumables for testing in human identification / forensics, food safety and veterinary medicine. Applied Testing sales grew 22% CER in 2012, contributing 8% of net sales. The business was boosted by an early 2012 software launch enabling Applied Testing customers to use many assays on the QIAsymphony system.

Among **Pharma** customers, demand for automation systems to increase R&D efficiency and researchers' use of the GeneGlobe portfolio of more than 60,000 assays drove growth of 5% CER in 2012. This growth was significant considering the industry's cost pressures as well as the ongoing consolidation and restructurings. Pharma represented 19% of net sales. In addition to providing innovative platforms and consumables, QIAGEN continues to partner with industry leaders to develop biomarkers and assays for use in translating discoveries into marketable drugs.

**Academia** represented 24% of net sales in 2012. Concerns about future U.S. and European public funding for research in the life sciences prompted cautious spending. Sales rose 1% CER, with growth in consumables offsetting weakness in instrument sales. Funding uncertainties are continuing in 2013. Longer term, universities are embracing translational research with partners in industry and government, so QIAGEN's strong relationships with academic labs are fueling growth across the value chain.

#### **Accelerating future growth**

QIAGEN focused on four strategic initiatives during 2012 to accelerate future growth. These initiatives leverage our business model and competitive advantages to create maximum value for customers, shareholders and other stakeholders. We believe we can generate consistent growth across all customer classes through steady progress on these initiatives.

**Drive Platform Success:** Our strategy for sustainable growth begins with innovative platforms that enable customers to improve the economics of their labs with streamlined, flexible automated workflows. A key focus for QIAGEN is securing placements of the QIAsymphony automation platform, the industry's first modular sample-to-result system that can process commercial assays as well as a broad range of laboratory-developed tests. QIAGEN exceeded the 2012 goal of reaching an installed base of more than 750 QIAsymphony platforms, and we are targeting the installed base to rise above 1,000 platforms during 2013.

We disclosed in 2012 the development of an integrated workflow for next-generation sequencing (NGS). We believe our workflow solution will enable the routine use of this breakthrough technology in areas such as clinical research and diagnostics. While NGS technologies already are transforming life science research, adoption for clinical purposes has been limited – primarily due to workflow challenges. QIAGEN's unique NGS workflow will provide an ecosystem of products and services to automate processes from primary sample to digital result. The launch campaigns for the first related products – which include consumables that simplify sample preparation and cancer gene panels for targeted NGS analysis – have been very successful. We expect to introduce our full NGS workflow during 2013 offering modular automation from biological samples through to clinical results, a broad range of assays and new bioinformatics to accelerate analysis time.

**Add Content:** A major priority for accelerating growth is adding novel content for use on the QIAsymphony family and other QIAGEN platforms. Expanding the menu of tests further enhances the value of our platforms to laboratories. We have a deep pipeline of new content in development, particularly in Molecular Diagnostics and Applied Testing.

In Molecular Diagnostics more than 35 new assays, spanning from blood-borne diseases to women's health, are under development for use on the QIAsymphony and Rotor-Gene Q systems. We focus on developing novel assays for regulatory approval, which helps drive adoption and reimbursement – as with our *therascreen*

companion diagnostics. Other submissions in the U.S. and Europe are expected to emerge from more than 15 alliances that QIAGEN has to co-develop and market companion diagnostics.

**Broaden Geographic Presence:** While the majority of net sales are in developed markets, a key growth strategy is to expand QIAGEN's presence in attractive regions around the world. Our top seven emerging markets – Brazil, Russia, India, China, South Korea, Mexico and Turkey – contributed 12% of net sales and rose 12% CER in 2012. We plan to enter additional countries as the business in those markets merits investment in a direct presence.

Our largest emerging market is China, which contributed more than 5% of net sales in 2012 and is growing at a double-digit rate as we increase market penetration through partnerships and novel content, such as the careHPV Test designed for use in areas that lack laboratory infrastructure. After two regulatory approvals for QIAasympathy modules in 2012, QIAGEN now offers Molecular Diagnostics customers in China the full QIAasympathy RGQ platform.

**Grow Efficiently and Effectively:** Building on our cultural ambitions in the area of focus, accountability and entrepreneurial decision-making, QIAGEN has been implementing operational improvements to enhance productivity and free up resources for reallocation to growth initiatives. For example, in 2012 we created two new Business Areas – Molecular Diagnostics and Life Sciences – to move decision-making closer to customers by integrating global marketing and R&D into customer-focused teams. Also in this spirit, regional marketing and sales teams were integrated into unified organizations to focus innovation on the most promising projects and establish greater accountability. We will continue to pursue opportunities to enhance efficiency and effectiveness throughout our organization, making proactive changes to leverage the growing value of our product portfolio to customers around the world.

#### **Improving life for customers**

We have defined our mission in the simplest terms: Making improvements in life possible. The pages that follow include examples as to how QIAGEN's products are helping to make improvements in life for people around the world.

A new wave of innovation and growth is emerging at QIAGEN, energized by the spirit of our employees. I want to express the appreciation of our Supervisory Board and Executive Committee to the 4,000 employees whose creativity, hard work and loyalty have made our success possible. We are committed to attracting and keeping the best people and teams in our industry. We also appreciate the more than 500,000 customers around the world who use QIAGEN's technologies. Customers are at the center of everything we do. In product development and daily interactions, we are always working to make life simpler and better for our customers.

QIAGEN is in an exciting phase. Our goals for 2013 focus on accelerating growth, delivering efficiency and effectiveness, further improving our position as an employer of choice, and exceeding the expectations of our customers. Doing so will enable us to achieve our mission of helping our customers make improvements in life, and creating value for our employees, shareholders and other stakeholders.

Thank you for your loyalty and support of QIAGEN.



Peer M. Schatz



PROF. DR.  
DETLEV H. RIESNER  
Chairman of the  
Supervisory Board

## To our Shareholders

The Supervisory Board wishes to thank all QIAGEN employees and members of the Executive Committee for the achievements in 2012, a year in which QIAGEN accelerated its pace of innovation and growth amid challenging economic conditions. We would also like to thank our shareholders, customers, business partners and other stakeholders for honoring QIAGEN with your continued collaboration and trust.

QIAGEN made significant progress during 2012 on strategic initiatives to drive innovation and growth. These actions led to growth for QIAGEN's products across all of our customer classes and regions. Multiple growth drivers are building momentum as we move into 2013. QIAGEN is expanding its leadership in Personalized Healthcare through its position as the partner of choice for molecular companion diagnostics as well as by building its molecular diagnostics assay portfolio. Growing placements of the QIAAsymphony automation platform are enabling the dissemination of molecular testing, while the QuantiFERON-TB test is improving the standard of care for latent tuberculosis (TB). Innovation goals for 2013 include entry into targeted areas of next-generation sequencing with workflow solutions for clinical research and human healthcare, as well as advancing QIAGEN's R&D pipeline of more than 35 molecular diagnostic assay projects. QIAGEN continues to improve efficiency and effectiveness, especially capabilities to address the needs of customers. The Supervisory Board is convinced that QIAGEN is well-positioned to achieve its goals for 2013 and fulfill its mission of making improvements in life possible.

As empowered by the Dutch Corporate Governance Code, the Supervisory Board devoted considerable time in 2012 to discussing QIAGEN's corporate strategy, main risks and opportunities, and an annual assessment by the Managing Board of the design and effectiveness of internal risk management and control systems as well as any significant changes in them. In addition, the Supervisory Board discussed and reviewed the functioning of its committees and individual members, its current composition, competence, succession schedule and desired profile in various meetings. The Supervisory Board came to the conclusion that it and the Managing Board were functioning properly.

The composition of the Managing Board changed during 2012 through the departure of two members – Dr. Joachim Schorr and Mr. Bernd Uder – after significant tenures with QIAGEN. Dr. Schorr joined QIAGEN in 1992 and was appointed Senior Vice President Research and Development and a Managing Director in 2004, while Mr. Uder joined QIAGEN in 2001 and was appointed Senior Vice President Sales and Marketing and Managing Director in 2004. The Supervisory Board would like to express our highest appreciation to Dr. Schorr and Mr. Uder for their important contributions to the success of QIAGEN and wish them all the best for their future endeavors. The Managing Board is now composed of Mr. Peer Schatz, QIAGEN's Chief Executive Officer, and Mr. Roland Sackers, QIAGEN's Chief Financial Officer.

The composition of the Supervisory Board is set to change in 2013 through proposals that will be put forward to shareholders at the next Annual General Meeting, which is scheduled for June 26, 2013. These changes are bringing new leadership talent and expertise into the Supervisory Board as well as ensuring a smooth generational transition. Four members of the Supervisory Board – Dr. Werner Brandt, Dr. Metin Colpan, Prof. Dr. Manfred Karobath and Elizabeth E. Tallett – will stand for re-election for one-year terms at this meeting. I will also stand for re-election to the Supervisory Board, and this will be for the last time, and my intention is to step down in 2014 after having served as Chairman of the Supervisory Board since 1996. The Joint Meeting has discussed a proposal for Dr. Brandt to become Chairman of the Supervisory Board in 2014 after he retires from his current position as a member of the Executive Board of SAP AG. Dr. Brandt, who has more than 30 years of leadership experience in the healthcare and IT industries, joined the Supervisory Board in 2007, and was also appointed in the same year as Chairman of the Audit Committee.

Two current members – Mr. Eric Hornnaess and Mr. Heino von Prondzynski – will not stand for re-election in 2013. We would like to thank both Mr. Hornnaess and Mr. von Prondzynski for their many years of service, insight and contributions. In addition, we are very pleased to propose Mr. Stéphane Bancel and Mr. Lawrence A. Rosen for election as independent candidates. Mr. Bancel, currently the founding CEO of Moderna Inc., is a highly regarded healthcare industry executive and former CEO of bioMérieux SA, while Mr. Rosen is CFO of Deutsche Post DHL and has spent more than 20 years in leadership positions at healthcare companies. Their perspectives, international experience in healthcare and other industries, as well as their diverse business backgrounds, will be valuable resources to QIAGEN expanding its leading position in Sample & Assay Technologies and their use in research, applied markets and molecular diagnostics. The profile of the Supervisory Board can be found on QIAGEN's website. The current composition fully complies with this profile.

In terms of the composition of the Supervisory Board and the Managing Board, new Dutch legislation took effect on January 1, 2013, requiring companies to pursue a policy of having at least 30% of the seats on the Managing Board and the Supervisory Board held by men and at least 30% held by women.

QIAGEN has a long-standing commitment to developing a diverse leadership team, including the Managing Board and the Supervisory Board, with a broad range of experience, skills and capabilities. In nominating candidates for these boards, QIAGEN supports the trend toward higher participation of women.

QIAGEN is committed to expanding diversity while pursuing individuals for these boards with a unique blend of scientific and commercial expertise and experience that will contribute to the future success of its business. Internally, management development programs support the career advancement of leaders regardless of gender and other factors. As a result, a number of women are in key leadership roles, particularly in commercial and operational positions around the world. In line with this long-standing commitment, the Supervisory Board will take the requirements of the Dutch law into account in the future when proposing members for election or re-election to its Board without compromising QIAGEN's commitment to hiring the best individuals for positions without any discrimination. QIAGEN's current governance structure has led to a reduction in the size of the Managing Board to two members, so achieving a diversity goal as measured solely by a percentage of overall membership is difficult to achieve. At the same time, QIAGEN has significantly increased the diversity of its senior leadership team and will continue to do so in the future.

The Supervisory Board has established an Audit Committee, a Compensation Committee and a Selection and Appointment (Nomination) Committee from among its members and can establish other committees as deemed beneficial. The Supervisory Board has approved charters under which each of the committees operates. These charters are published on our website ([www.qiagen.com](http://www.qiagen.com)).

Further detailed information on the composition of the Supervisory Board and its committees, the number of committee meetings held in 2012 and the main topics of discussion, the independence of its members and their remuneration, as well as other information on the Supervisory Board, can be found in the Corporate Governance Report, which is an integral part of this Annual Report.

The Supervisory Board met seven times during 2012 with regular attendance of the members of the Managing Board for certain agenda items. The Supervisory Board also met to review and discuss agenda items in the absence of the Managing Board members, such as to review performance and strategy as well as to discuss compensation matters. We are pleased to report that all members of the Supervisory Board attended every Supervisory Board meeting in 2012. Information about the Supervisory Board members, including positions held on other boards, is included in the Corporate Governance Report. All members of the Supervisory Board had adequate time available to give sufficient attention to the concerns of the company.

Through its Compensation Committee, the Supervisory Board executed and monitored compliance with the Remuneration Policy approved at the Annual General Meeting held on June 14, 2005. Compensation of Managing Board members consists of a fixed salary and variable components. Variable compensation includes one-time and annual payments linked to business performance (bonuses) as well as long-term incentives containing risk elements, such as stock options or other equity-based compensation, and pension plans. The Remuneration Policy and the various aspects of compensation, including the detailed remuneration of individual Managing Board members, are described in the Remuneration Report, which is also available on QIAGEN's website. Information on QIAGEN's activities was communicated by the Managing Board to the Supervisory Board through regular meetings and business reports.

All members of the Supervisory Board fulfill the independence criteria as defined by the Marketplace Rules of the NASDAQ Stock Market and the Dutch Corporate Governance Code, with the exception of Dr. Metin Colpan, a founder and former CEO of QIAGEN.

QIAGEN N.V. is a company organized under the laws of the Netherlands and has an international network of subsidiaries. The Supervisory Board follows the principle of increasing shareholder value as we

represent the interests of all stakeholders, including shareholders, and has always pursued the highest standards in Corporate Governance.

QIAGEN is committed to a corporate governance structure that best suits its business and stakeholders, and that complies with relevant rules and regulations. Since 1997, QIAGEN has endorsed the recommendations made in the report of the Netherlands Committee on Corporate Governance, which was replaced by the Dutch Corporate Governance Code effective January 1, 2004, and amended and restated effective January 1, 2009. Our policy is to follow the guidelines of Good Practice of Corporate Governance as described in the Dutch Corporate Governance Code, although some minor deviations may result from the impact of factors such as legal requirements imposed on QIAGEN or industry standards.

QIAGEN is also subject to the rules regarding Corporate Governance set by NASDAQ, where its common shares have been listed since 1996. In addition, QIAGEN has adopted the standards set by the Corporate Governance Code of Germany, where its common shares have been listed since 1997. QIAGEN provides detailed disclosure in the Corporate Governance Report regarding compliance with the German and Dutch Corporate Governance Codes.

QIAGEN believes all of its operations are carried out in accordance with legal frameworks, including Dutch Corporate Law, U.S. laws and regulations, and the laws of the German capital market, in particular the Wertpapierhandelsgesetz.

QIAGEN's common shares are registered and traded in the U.S. on the NASDAQ Global Select Market and in Germany on the Frankfurt Stock Exchange in the Prime Standard segment. Shareholders in the U.S. and Europe hold the majority of common shares. Among topics the Supervisory Board discussed during 2012 were strategies for the allocation of capital to enhance returns to shareholders, and a \$100 million share repurchase program was launched in late 2012.

In this Annual Report, the financial statements for 2012 are presented as prepared by the Managing Board, audited by Ernst & Young LLP (Independent Registered Public Accounting Firm), and examined and approved by the Supervisory Board.

Venlo, the Netherlands, March 2013



Prof. Dr. Detlev H. Riesner  
Chairman of the Supervisory Board

# Breaking the code: companion diagnostics

AUTHOR: Alexandra Smit-Stachowski

PHOTOGRAPHY: Andreas Fechner





KULVINDER SHINJI  
(staff nurse) checks the condition of  
a cancer patient at the Queen Elizabeth  
Hospital Birmingham, England.

# Companion diagnostics are transforming modern medicine by using each patient's genomic information to guide treatment decisions. The benefits become clear in the cancer clinic at the Queen Elizabeth Hospital Birmingham, England.

Visitors to Queen Elizabeth Hospital in Birmingham, England, have a unique opportunity to walk through a historic location known for advances in medicine, and at the same time experience a place where modern medical breakthroughs are being made. The first buildings were built in the 1930s and opened by King George VI and Queen Elizabeth, who was the namesake of the original and new hospitals and would later go on to become the Queen Mother. The new Queen Elizabeth Hospital Birmingham (QEHB) opened in 2012 with a commitment to excellence in medicine.

The hospital's reputation is built on its rank as the largest renal transplant program in the United Kingdom and also as a national specialist service center for organ transplants. The areas of expertise go beyond organ transplantation, and the staff of QEHB are also known for being at the forefront of advancing the treatment of cancer.

Visitors on the ground floor, where the day clinics are located, are directed to the right locations by a small group of volunteers. British Armed Forces members in uniform pepper the crowds walking through the hallways of this hospital, where about 120,000 patients are treated annually.

What these visitors do not see, however, are the underground offices and laboratories where teams of oncologists and pathologists are hard at work employing the latest molecular technologies and targeted therapies to deliver on the promise of personalized healthcare. These pioneering, high-tech

approaches are quickly becoming the standard of care in treatment – a process that is occurring at many hospitals around the world.

Many of the innovations shaping the daily treatment of patients in Birmingham have their origins about 90 miles away on the outskirts of Manchester, located next to the city's university complex. In a traditional red-brick building that forms a striking contrast to the glossy, high-tech face of QEHB, a rapidly growing team of more than 150 QIAGEN employees work on the development of new companion diagnostics slated to guide treatments with novel drug compounds that will sooner or later find their way into medical practice in Birmingham and elsewhere.



DR. STEPHEN LITTLE AND VINCENT FERT (f.l.t.r.) say QIAGEN's expertise is bringing Personalized Healthcare to reality for patients around the world.



~50%

of KRAS testing volume in the U.S.  
is based on QIAGEN technologies



DR. PHILIPPE TANIÈRE  
has a laboratory that relies on standardized, regulatory-approved tests for KRAS, BRAF and EGFR to break the cellular code of cancer and find the right treatment for each patient.

»We look into the cells – we extract DNA or even RNA and we look at very specific alterations in genes or levels of expression of genes.«

**DR. PHILIPPE TANIÈRE**

Consultant Histopathologist, QEHB

In one of the conference rooms, a group of QIAGEN managers from around the world gather to discuss the progress of ongoing projects. Leading the meeting is Vincent Fert, a French scientist and entrepreneur who is now a senior executive leading QIAGEN's initiatives in Personalized Healthcare. He was a founder of Ipsogen, a global leader in diagnostics for blood cancers that became part of QIAGEN in 2011.

"QIAGEN has demonstrated that we have the right technologies and can develop, obtain regulatory approvals, achieve strong reimbursement levels and also commercialize assays that are bringing the power of Personalized Healthcare to patients and healthcare systems around the world. Our commitment to innovation means that patients and physicians are getting guidance for crucial medical decisions from the precise, reliable information provided by the *therascreen* portfolio of companion diagnostics," Fert says.

The 2012 FDA approval of QIAGEN's *therascreen* KRAS test kit on the Rotor-Gene Q MDx and its subsequent U.S. launch marked not only a significant milestone for QIAGEN's business, but also for Personalized Healthcare in general. Only a few months later, approximately 50% of the corresponding testing volume in the U.S. had converted from "laboratory-developed tests" to QIAGEN's FDA-approved companion diagnostic. And the KRAS launch has provided a model for QIAGEN's co-development and regulatory submission of other novel drug-diagnostic combinations.

"With the U.S. launch of our KRAS companion diagnostic, QIAGEN has achieved a major milestone on the promise in Personalized Healthcare," says Fert. "QIAGEN's team carved out the path to FDA approval for a standardized, highly reliable test paired with an important drug from our pharma industry partner for metastatic colorectal cancer. We took a proactive approach to securing reimbursement from payers based on the value of our companion diagnostic and won market acceptance with rapid conversion to the FDA-approved test."

Asked about the key to QIAGEN's progress in Personalized Healthcare, Fert says, "We're successful because we have two sets of customers – the pharmaceutical industry, which needs to target its drugs to succeed, and the diagnostic labs that serve healthcare providers – and our business model and capabilities allow us to meet the needs of both of them. We can translate the needs of one world into the requirements of the other world."

QIAGEN brings special skills to co-development programs with pharmaceutical R&D. "Cancer is very fragmented," explains Dr. Stephen Little, a pioneer in companion diagnostics and now a senior advisor to QIAGEN on Personalized Healthcare. For every oncology drug in development, researchers investigate various potential diagnostics. Then, he says, the researchers choose the biomarker that will be used to select suitable patients for the drug, and that is where QIAGEN comes in. "Our role is to develop a diagnostic test which will allow reliable measurement of the biomarker in clinical sam-

ples to allow the selection of patients most likely to benefit from the therapy.”

Dr. Paul Ravello, a commercially savvy scientist with highly regarded regulatory experience, says the relationship with collaborators is critical. His background is scientific; he developed some of the assays that QIAGEN sells now – “the EGFR assay, our KRAS assay in their earliest forms.” He also has had a lot of external, customer-facing exposure working with pharma partners. Essentially, he says, the role of project management is two-fold.

“I’m lucky enough to have a technical background, so I know what’s realistic. The way the companion diagnostics business is run is – what’s the critical point on a companion diagnostic timeline?” He knows what is needed – after all, QIAGEN is one of the pioneers in this area. “In terms of companion diagnostics, if you were to look on the FDA website there’s only ever been about 15 companion diagnostics approved and of those, in terms of molecular diagnosis using PCR, there’s only two – of which KRAS is in terms of reach by far the most significant.”

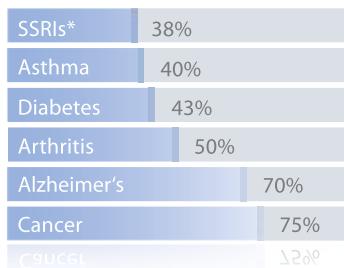
Dr. Ravello adds, “We are striving with our partners to identify the most appropriate biomarker as early as possible in clinical development. Our role then becomes to develop the companion diagnostic test paired with the drug so that late-stage clinical trials – the last and most expensive trials required before submission – take place with the market-ready version of our test. This provides many benefits, particularly the data to support two important aspects – approval of the drug, and also regulatory approval of the companion diagnostic.”

QIAGEN’s companion diagnostics are aimed at the regulated marketplace – so they must be backed by a strong regulatory team. Of the 150 staffers in Manchester, 50% are in product development, while others such as Dr. Ravello focus on day-to-day coordination with QIAGEN’s pharmaceutical partners and regulatory bodies in international markets.

Working with the FDA on the KRAS submission was part of a learning process, as this was a new field and it is a complex system. QIAGEN executives participated in many discussions with regulators, exploring and defining frameworks for successful adoption of Personalized Healthcare. In 2011 the FDA produced draft guidance documentation, which shows the difficult path trodden by QIAGEN and others to establish this new market. “I think a lot of what is reflected in the regulatory guidelines is the result of collaboration with mutual respect and a common goal to establish a viable framework to generate the highest possible benefits from pairing medicines with companion diagnostics,” Dr. Ravello believes.

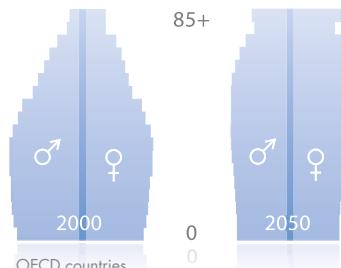
At the front end of establishing new QIAGEN collaborations and partnerships for the development of companion diagnostics to support novel pharmaceuticals is the Companion Diagnostics Partnership team. Richard Watts, Vice President of Companion Diagnostics Partnerships Americas, is a dynamic executive, helping partners forge valuable partnerships with QIAGEN, such as the comprehensive collaboration agreement he negotiated with Bayer HealthCare in 2012 that focuses on both existing and new biomarkers in QIAGEN’s portfolio.

# Personalized Healthcare addresses many treatment and cost challenges



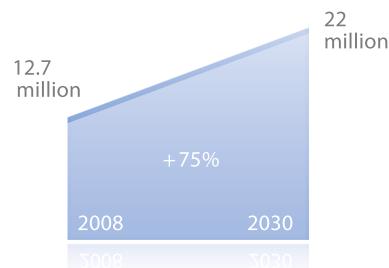
## Drug failures

Medicines in general are ineffective in many patients, in part due to genetic variations.



## Aging population

Demographics are driving the need for better, more effective treatments for chronic diseases.



## Example: Cancer

The global incidence of cancer is estimated to almost double by 2030.

\*Selective serotonin reuptake inhibitors, a popular antidepressant type

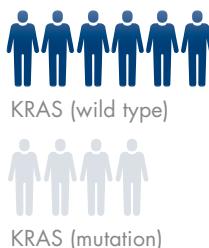
# Easy process to select patients for medicines

## Testing



Get molecular information to personalize treatment.

## Stratification



~60%  
Targeted therapy

~40%  
Consider other options

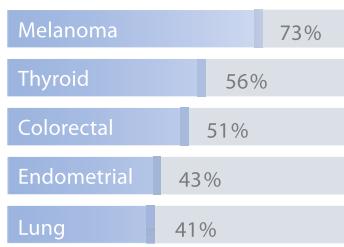
## Benefits

- Avoid "trial-and-error" medicine
- Improve treatment outcomes
- Save healthcare resources

# Benefits for all stakeholders

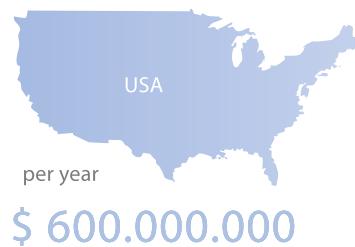
## Targeting diseases

Many tumors are associated with genetic mutations that could be targeted by novel drugs.



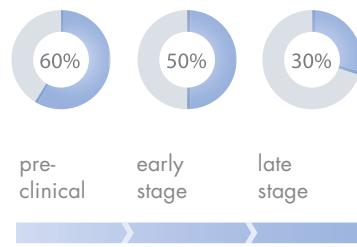
## Cost savings

As one example, considerable savings from companion diagnostics in colorectal cancer patients.



## Biomarkers fuel new medicines

Molecular information a key driver of pharmaceutical R&D pipelines.



For references, see page 212

»Targeted therapies, guided by the diagnostic, are a very good thing from a health economics perspective, but more importantly from a patient's perspective. They're getting the right drugs and they're living a good quality of life.«

RICHARD WATTS

Vice President of Companion Diagnostics Partnerships Americas, QIAGEN



A tumor sample embedded in paraffin is prepared for DNA extraction and testing with a companion diagnostic that will guide the treatment.

Richard Watts has a clear understanding about the needs of pharmaceutical companies – and what QIAGEN can deliver – and how to bring this together in effective collaborations. “Our pharmaceutical partners are driven by the science – which must be robust. QIAGEN is unique in having a very wide portfolio of intellectual property and products which meet the requirements of molecular diagnostics,” Mr. Watts says.

“Targeted therapies, guided by the diagnostic, are a very good thing from a health economics perspective, but more importantly from a patient’s perspective. They’re getting the right drugs and they’re living a good quality of life,” Mr. Watts states.

The pharmaceutical industry is bringing personalized healthcare to reality, Mr. Watts has found. “There are many different names for this – some people call it stratified medicine, some say precision medicine, some people say personalized medicine – at the end of the day we’re developing therapies and diagnostics which are enabling us to bring the power of new medicines to patients who can benefit most,” he says.

Current programs at QIAGEN address therapeutic areas that include cancer, autoimmune conditions, and Central Nervous System disorders, involving many new drugs in clinical development.

Asked about the future, Dr. Ravetto says, “We know there’s going to be a desire to have multiple tests for a single patient – so you do a KRAS test, you might do an EGFR test and then there are other less prevalent mutations, which are all related. You’ll be able to do a panel of tests – but they all will be

able to develop a picture as to what the best therapy is for the patient.”

Mr. Watts sees the future of companion diagnostics evolving further: “Infectious disease has in fact led the space of companion diagnostic test development, through HIV testing, through other areas as well – but today it’s predominantly oncology. We’re now moving into more complex diseases such as autoimmune diseases and rheumatoid arthritis, other rheumatology-based diseases, and we’re also expanding into more complex diseases such as Alzheimer’s and Parkinson’s.”

The buzz, however, is about next-generation sequencing (NGS). “This breakthrough technology will be highly complementary to our established molecular testing with real-time PCR, and it will allow us to generate massive amounts of information on a patient. However, more data is not always better since it will be critical to understand the clinical relevance in terms of treatment options,” Mr. Watts says. QIAGEN is preparing to introduce a comprehensive sample-to-result NGS workflow to address the needs of customers for biomedical and clinical applications, including meaningful analysis of the massive amounts of information generated.

Further afield in Birmingham are two long-time colleagues who put companion diagnostics to practical use: Consultant histopathologist Dr. Philippe Taniere and oncologist Dr. Neil Steven at the Queen Elizabeth Hospital Birmingham.

Passionate about his patients and getting to the bottom of cancer, Dr. Steven takes time to explain the complicated cancer process in a way that is easy to

»It's obvious to us all that we can't afford everything under all circumstances, so stratifying medicine becomes increasingly important to healthcare and to our patients.«

DR. NEIL STEVEN

Oncologist, QEHB

DR. NEIL STEVEN, oncologist, says doctors are breaking the cellular code to predict the outcome of cancer treatments with companion diagnostics.



understand. "There's an analogy I would use – breaking ciphers. To some extent, that's what we're doing in terms of the way the cells work," he explains. "You have a very complex system within a cell – it's quite difficult to pull apart – so if you can find an encoded message, it can give you a handle on how these different bits fit together. You can use that to try and break the cellular code."

Dr. Taniere heads the University Hospitals Birmingham NHS Foundation Trust's molecular pathology service integrated in the histopathology department, which is based in the Trust's QEHB and breaks the code of cancer on a daily basis. The dynamic Frenchman has been in Britain for many years building the formidable molecular pathology

unit. The whole team has 30 scientists, technicians, laboratory assistants in the labs and 10 secretaries, who deal with about 30,000 cases a year.

"We look into the cells – we extract DNA or even RNA and we look at very specific alterations in genes or levels of expression of genes," Dr. Taniere says. Where companies like QIAGEN have been "extremely helpful and supportive, they've provided us with kits and equipment, which have been set up to work in what we have in routine practice – in terms of solutions allowing us to process tumor samples and kits targeting the specific alterations which we need."

Since 2009, his team has done over 100 KRAS tests every month for colorectal cancer patients from the area, from many other hospitals in England and some referrals from abroad. BRAF is a gene that is tested in melanomas, so Dr. Taniere also processes more than 100 BRAF tests a month. "We also test 200 lung cancers for EGFR mutation. So in sum it has already become a big volume of tests that have to be processed, which is very exciting," he says.

Adoption of companion diagnostics "is extremely vital and millions are invested. When it comes to diagnostics, it has to be fully validated, it has to be," Dr. Taniere explains. Along with growing demand for molecular tests, this prompts many laboratories in this area to shift their entire workflows to automated solutions such as QIAGEN's QIAAsymphony RGQ,

~5,000

tests for the KRAS, EGFR and BRAF biomarkers a year show the need for laboratory automation.

which not only help to cope with rising test volumes but also ensure a higher comparability of results and minimize the risk of sample mix-ups.

Accordingly, all kits Dr. Taniere and his team use for the diagnosis need to have official validation such as the CE-Mark in Europe or FDA approval in the U.S. He sees the future as technology-driven and constantly evolving, while keeping with accepted standards – a widespread view that is reflected in QIAGEN's efforts to further expand the menu of validated tests in Personalized Healthcare and other application areas.

Asked if he believes next-generation sequencing or multiplex testing will become the only way of the future, he replies, "I don't believe one technique will replace everything – we need to cover all the patients, every type of tumor, every alteration – which makes it more exciting. But we need to have some companies with these wide panels of kits and techniques working and upgraded to follow the needs."

Additionally, the challenge is to translate the vast amount of molecular information into actionable clinical decisions. "The KRAS test – for example – helps us to identify patients that will benefit from novel targeted treatments. But what do we do with the others?" Dr. Taniere states simply, "We don't have three other drugs – so currently they go back to classical chemo which is not selective." The issue

is extremely complex. Dr. Taniere concludes with a question, "So with next-generation sequencing, I can test any tumor for everything I can possibly imagine. But what do you do, if the data is not validated and if you don't have the treatment?"

Another trend he sees is an increasing focus on RNA: "Most of the kits now are assessing DNA alterations, but more and more we need information on the presence of the expression of fusion genes, because there are lots of targeted drugs under validation or already on the market, which are targeting not DNA alterations but chromosomal translocations – the kits we have at the moment don't do that."

On the ground level of the hospital is a waiting room for cancer patients, filled with people sitting patiently, waiting for their appointments with doctors, including Dr. Steven.

Glancing around, the visitors range from the regulars who are prepared, one clutching a book to read, a student trying to learn from her course book and others watching the clock. Reality dawns when a young couple emerges ashen-faced after talking to Dr. Steven, clutching papers and talking earnestly to the staff – who matter-of-factly advise the couple accordingly.

# 120,000

patients a year come to the Queen Elizabeth Hospital Birmingham, England.

Upstairs is the cancer clinic, which is also run by Dr. Steven. The ward is a circular room with the nursing center in the middle, hospital beds lining the walls and comfy couches well-placed for the visitors returning for follow-up checks. The patients are good-natured and the atmosphere is homelike as the nursing staff is sunny, sympathetic and compassionate. The nurses talk quietly to those being seen to, and sometimes the brightly-colored curtains are drawn close around the beds. But mostly those visiting rest on the large leather chairs.

One of the patients is Allan Robbins, name changed to protect his privacy, suffering from rectal cancer and on the sixth day following surgery. Looking pale yet quietly confident, the older man is resting in his room in the ward, lying on his side and valiantly drinking a cooling cup of tea with a straw.

"I had symptoms and thought 'It's just hemorrhoids' but eventually went to have it checked out," he admits wryly. "In early June the GP checked me over and the week after that I was here. I had a series of scans, MRI and CT scans and biopsies to decide what the problem was and was referred to the oncologist who put me on a chemo- and radiotherapy course for five weeks. There was then quite a big gap and I recovered from it. I was going out and driving." His process also included being tested for KRAS to help guide treatment options.

Asked what would make his life easier, Mr. Robbins thinks and replies, "If I had one person in charge of me, that would be nice." With cancer treatment already heading toward use of multiplex testing and next-generation sequencing, the way of the future could well be to equip each patient's physician with all of the information needed to evaluate options and select the best possible treatment.

Doctors are beginning to be in position to predict the outcome of treatments, Dr. Steven says. "Essentially we use a predictive marker – if people have KRAS mutations, we do not use these antibodies. If they are not KRAS mutated, then it becomes feasible to use them." He continues, "It's built into our clinical algorithms – it's also built into our funding algorithms – we would not be permitted funding for using these expensive drugs if that's mutated. Both our reimbursement system and our clinical decision-making are critically dependent on what goes on in our pathology department."

Dr. Steven adds, "As we move forward with targeted treatments, then having this kind of molecular diagnostics becomes very important, both in terms of personalized medicine for patients and in terms of the way the funding works. It's obvious to us all that we can't afford everything under all circumstances, so stratifying medicine becomes increasingly important to healthcare and to our patients."

Studies demonstrate that cancer drugs work only in about 25% of all patients. Companion diagnostics help to match the right therapy with the right patient.



# A view from inside the lab

AUTHOR: Przemek Jedrysiak

PHOTOGRAPHY: Andreas Fechner





Automated platforms such as the QIAsymphony RGQ help diagnostic and research laboratories to increase efficiency and quality of results.

# What's important to a diagnostics laboratory?

Ian Collacott of the Aberdeen Royal Infirmary wants to manage workflow with automation that enables his lab to get results for patients in a timely, cost-effective way.

IAN COLLACOTT says automation is essential for modern molecular diagnostic laboratories processing large sample volumes.



Mr. Collacott, could you please briefly introduce your lab?

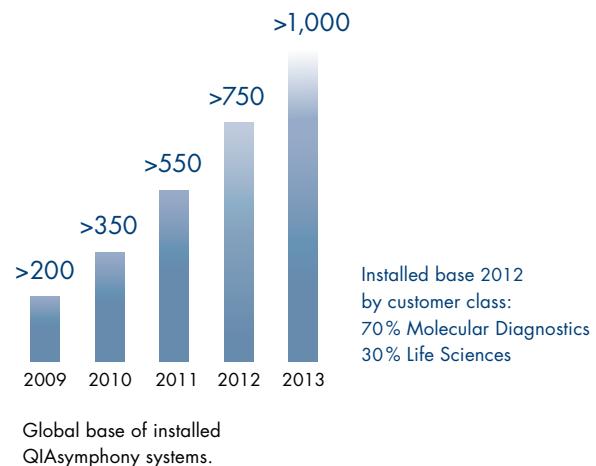
We provide microbiology and virology testing to about 600,000 people in Northeastern Scotland. The Department of Laboratory Medicine here at the Aberdeen Royal Infirmary has a staff of about 400, and the combined microbiology-virology lab has about 70-80 staff members. Overall, it's a quite comprehensive regional virology and microbiology service. We process about 500,000 samples a year in microbiology, and around 60,000 blood and 12,000 other sample types such as swabs, urine or cerebrospinal fluid in virology.

What are the most frequently performed tests at your lab?

In blood testing, the most common tests would be for viruses such as hepatitis B (HBV), hepatitis C (HCV) or the human immunodeficiency virus (HIV). We also conduct a few thousand norovirus tests a year. In addition, tests are being done to screen patients who have undergone transplants for infections such as cytomegalovirus (CMV) or Epstein-Barr virus (EBV). We also have a large number of respiratory virus samples covering various pathogens, and these are around 5,000 a year.

How are these tests being performed?

We use a mix of immunological and molecular assays. Most of the molecular testing is done in a semi-automated process using various instruments from different vendors. However, we've started to transfer several tests to the QIAAsymphony RGQ platform which has enabled us to greatly improve automation. We are already routinely using the *artus* HCV and HIV viral load test kits on this platform and have recently added the *artus* EBV and CMV kits as well. This is much easier than semi-automated workflows: We simply load the samples, start the extraction run for the nucleic acids of interest, and then tell the QIAAsymphony what assay should be prepared. The only manual step is to load the ring holding the tests from the QIAAsymphony AS to the Rotor-Gene Q for the real-time PCR process to



generate the test results. So there is very low hands-on time. The use of barcode readers and standardized software also means we have far less variability in test results and a far lower risk for mixing up samples.

**When did you start using the QIAsymphony and what factors convinced you to choose this system?**  
We started evaluating the platform in late 2011 as one of the systems under consideration for a tender. We assigned scores for various factors such as the range of commercially available tests, their sensitivity, the sample processing capacity of the machines, their cost-effectiveness and other features. One of the main points for us was that the system must be "open," meaning that it could automatically process both our own laboratory-developed tests as well as commercial kits. But the most important factor was convenience – we wanted a system where we just have to load the patient samples at one end and take the tubes off at the other end and load them into a real-time PCR cycler to generate the test results.

#### What does the split between automated and semi-automated tests look like?

Currently about one-third of the samples are processed on the QIAsymphony and two-thirds on the semi-automated set-up. So we still have a significant volume being done in a semi-automated manner.

But we're trying to move more tests over to the QIAsymphony, because it requires less hands-on time from our staff and is also a more secure system. I think that we will keep expanding the test menu on the QIAsymphony during the next one to two years.

#### So you are trying to automate as much of your work as possible?

Yes, that's correct. We want to avoid having a staff member sit down and manually pipette all these reagents and samples. The automation does it for you. I think that the way ahead is definitely for more automation, and this will help us to more efficiently produce results and cope with an increasing workload. It would be absolutely impossible for us to handle our current workload using only manual methods. Automation is absolutely essential, especially as there is an increasing demand to deliver more rapid test results in order to improve patient care.

#### When did you initially start using instruments for molecular testing? Is there a certain threshold in terms of volume when automation becomes attractive?

For molecular testing, we started using automated extraction methods about six to seven years ago, and that was actually with a QIAGEN BioRobot. When we started doing real-time PCR tests, we first used a completely manual protocol. As soon as we

» Automation is absolutely essential, especially as there is an increasing demand to deliver more rapid test results to improve patient care.«

IAN COLLACOTT

Virus Laboratory, Aberdeen Royal Infirmary

reached about 20 samples a day, it became worthwhile to invest in an instrument. Processing this amount of tests a day using a completely manual method ties up a skilled person for the good part of the day, and the risk of contamination is far greater. So I would say that if your workload reaches about 100 samples a week, then you should be using automated methods. It is far more efficient, cost-effective and reliable than using manual methods.

#### How do you measure the efficiency of your workflow?

We have statistics on all of our tests. We know how many tests are being conducted, what test methods are used, and the time from receiving a sample to reporting the results. We also participate in surveys to benchmark our performance against other laboratories. We compare ourselves to other teaching hospitals in the United Kingdom and measure our efficiency in terms of cost per test, number of staff needed to perform a test, workload and other factors. The results show that we have a good system and efficient processes.

#### What areas do you see for improvement in lab automation?

It would be very desirable to have an even higher grade of flexibility in processing samples for mo-

lecular testing. Also, it is very important that we improve the integration of instruments into laboratory information systems, so that reports and test results are automatically loaded to the system. But I think that if we look at the history of automation over the last decade, we can see these needs already starting to be addressed. We started eight years ago with a fairly simple QIAGEN instrument that only did sample extraction, and today we have a very sophisticated instrument with QIAasympathy, which can automate the process from sample to result. So yes, I think manufacturers understand the needs of laboratories and are actively developing products to help improve our processes.

#### Mr. Ian Collacott

is the Chief Biomedical Scientist in Virology at the Aberdeen Royal Infirmary. He has worked in virology since 1974 and joined the institute in 1992. His broad interests include, in particular, molecular diagnostics, blood-borne and respiratory viruses. Since 2002 he has been an examiner in Virology for the Institute of Biomedical Science in the UK.

**QIAsymphony RGQ:**

The industry's first modular system that can process commercial assays as well as a broad range of laboratory-developed tests from sample to clinical result.

**Workflow**

- Full walk-away automation
- Continuous loading
- Parallel assay processing
- Intuitive software

**Menu consolidation**

- Broad commercialized assay menu
- Compatibility with all specimens and volumes
- Largest range of applications

**Open platform**

- Flexibility for laboratory-developed tests
- Broad range of protocols
- Compatibility with existing systems

## Broad test menu driving growth

	Molecular Diagnostics	Applied Testing	Pharma	Academia
Profiling diseases	<i>artus, care</i>			
Personalized Healthcare	<i>therascreen, ipsogen</i>		<i>therascreen, ipsogen</i>	
Pathway analysis			<i>GeneGlobe</i>	<i>GeneGlobe</i>
Food safety		<i>mericon</i>		
Veterinary medicine		<i>cador, virotype, bactotype</i>		
Human ID&Forensics		<i>Investigator</i>		
Quality assurance			<i>Certal</i>	

# Translating knowledge into medicines

AUTHORS: Victoria Fei and Richard M. Johnson

PHOTOGRAPHY: Andreas Fechner





A researcher at the Shanghai Clinical Research Center examines a library of clinical tumor samples.

Pharmaceutical R&D is focusing on translational medicine: moving new drugs “from bench to bedside.” When a global pharma company attacks liver cancer, QIAGEN and a network of partners add unique value.

Sitting in his office overlooking Nanjing Road West in Shanghai, one of the busiest streets in one of the world’s most bustling cities, Dr. Tao Jingsong brings a calm, passionate focus to his mission with Sanofi, a leading global pharmaceutical company.

As Sanofi’s Senior Clinical Research Director, Asia Pacific R&D, Dr. Tao is committed to creating new drugs that make a difference in the lives of people passing by outside. This mission has brought him into a dynamic new partnership with QIAGEN to advance healthcare for people in the region.

In 2012 QIAGEN launched an innovative Translational Medicine Center on Suzhou’s BioBAY life sciences campus to help pharma and biotech companies accelerate the development and commercialization of new therapies. Translational medicine is a rapidly emerging discipline that aims to move scientific knowledge more rapidly “from the bench to bedside.” New ways of working are being implemented to quickly create clinically relevant medicines from research breakthroughs, and advance them rapidly through development and regulatory approval processes to commercialization.

Sanofi is one of the first pharmaceutical companies to partner with this new QIAGEN initiative, which is supported by experts at QIAGEN’s center of excellence in molecular pathway analysis technologies in Frederick, Maryland. The collaboration focuses on a novel Sanofi compound in development for treatment of liver cancers linked to hepatitis B infections. The infection is considered a serious health

threat in the region. In China alone, estimates indicate as many as 10% of the country’s 1.3 billion people have a hepatitis B infection, and 350,000 new cases of liver cancer are reported each year.

“Sanofi is good at making drugs, while QIAGEN has developed powerful tools for discovering and validating biomarkers and genetic mutations that are important in translational medicine,” Dr. Tao says. “QIAGEN and Sanofi have a common purpose, so our collaboration is a perfect match to meet the needs of patients.”

#### **Strengths work for global pharma**

QIAGEN has unique competitive advantages in this field covering the entire pharmaceutical R&D continuum. The scientific strengths, products and track record of QIAGEN span the drug discovery and development process from basic research and identification of drug targets, through preclinical testing, to clinical trials for safety and efficacy, on to regulatory reviews and into commercialization of companion diagnostics that guide the use of medicines.

“Drug discovery and development is changing at a rapid pace. Pharma companies are increasingly seeking to develop medicines targeting aberrations in molecular pathways and the underlying causes of diseases,” says Dr. Xiao Zeng, Vice President Genomic Assays and Content Development at QIAGEN Frederick. “Given the tough economic conditions and the number of medicines losing patent protection, pharma companies also are under pressure to improve R&D productivity and reduce

» QIAGEN and Sanofi have a common purpose, so our collaboration is a perfect match to meet the needs of patients.«

DR. TAO JINGSONG

Senior Clinical Research Director, Asia Pacific R&D, Sanofi

costs. QIAGEN is increasingly seen as a global partner to support their initiatives to make R&D processes more effective and span the translational bridge from research labs to the clinic. In this way, we add value.”

As a pioneer in molecular biology, QIAGEN has developed experience at all stages of the R&D process. This expertise is built on a foundation of global leadership in Sample Technologies that enable the first steps in transforming a biological sample into valuable molecular information by isolating, purifying and stabilizing the target DNA, RNA or proteins.

Another competitive advantage for QIAGEN is the ecosystem supporting workflows, including software and bioinformatics. The online GeneGlobe portal, for example, offers access to more than 60,000 well-defined and characterized molecular assays – either preconfigured or customized – to expedite disease pathway analysis.

For preclinical analysis of drug candidates, labs are enhancing productivity by using automated workflows such as the breakthrough QIAAsymphony modular platform, which offers sample-to-result processing of biological samples.

When a drug moves to clinical development, QIAGEN technologies are delivering valuable molecular information to characterize the health status of a patient. Assays targeting disease biomarkers are helping pharma R&D teams to design



DR. TAO JINGSONG (Sanofi) aims to make a difference in the lives of people across China with an innovative new drug for liver cancer.

clinical trials, select patients most likely to benefit from a compound, monitor disease progression and gain insights for future drug development.

In addition to offering workflow solutions based on real-time PCR, QIAGEN is developing a portfolio of products based on next-generation sequencing (NGS) technology. QIAGEN's strategic goal is to make NGS, now limited mostly to life science research, a routine and cost-effective tool in clinical research and healthcare. The initiative seeks to address workflow challenges that currently hamper the adoption of NGS, particularly the time required for data analysis, sequencing costs and regulatory uncertainties.

# 750,000

new liver cancer cases  
a year worldwide

#### A collaboration takes shape

The idea for the Sanofi-QIAGEN collaboration in translational medicine was sparked when leaders of the companies met at the World Economic Forum in Davos in January 2012.

In April 2012, QIAGEN's Dr. Zeng and Richard Watts, Vice President of Companion Diagnostics Partnerships Americas, traveled to Sanofi's R&D hub in Boston and met with 90 global R&D staff members to discuss how the two companies could translate an academic discovery in China into a promising pharmaceutical product.

The outcome of this meeting and further interactions with QIAGEN's team in China was a collaboration that focuses on a novel compound under development by Sanofi with potential for treatment of liver cancer, an often-fatal disease. Nearly 750,000 cases of liver cancer were reported worldwide in 2008, with China accounting for nearly half of the cases. The World Health Organization estimates the mortality rate at more than 90%.

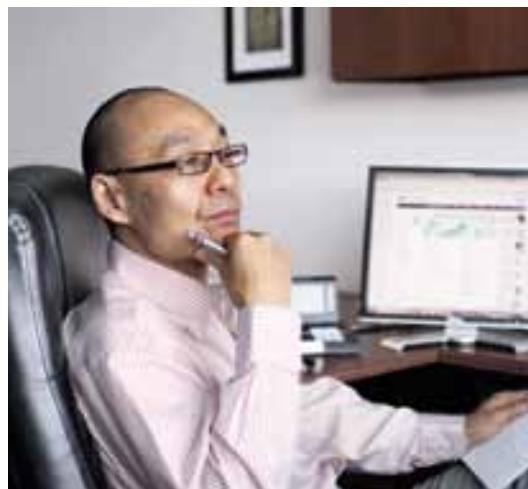
The Sanofi compound is a potential first-in-class agent for treatment of liver cancer that binds with specific cellular receptors to block a signaling pathway known to promote growth of blood vessels in tumors. The aim is to create a drug that "starves" the cancer cells.

Moving this compound into human clinical trials involves a common challenge in drug development: For genetic reasons, not everyone responds the same way to any particular drug.

"We need to find patients who can benefit from this treatment," Dr. Tao says. "For treatment, first of all, we want to know what is the main mutation that is responsible, and then we can find a drug to target this mutation. Cancer is very complex. It could be one mutation. It could be multiple mutations. Everybody is different. We want to find a method to test patients."

QIAGEN's experience in creating assays to predict drug success has produced diagnostics for biomarkers such as KRAS, EGFR, BRAF and JAK2 – driving growth in Personalized Healthcare. The same skills are helping Pharma R&D teams achieve success in clinical development.

Sanofi's R&D team quickly approved a collaboration with QIAGEN to help prepare for clinical trials, based on the Company's experience in developing assays for biomarkers in several major cancers.



DR. XIAO ZENG says QIAGEN is a partner in translational medicine for pharma companies under pressure to improve R&D productivity.



Scientists at the Shanghai Clinical Research Center, one of QIAGEN's partners, are aiding the liver cancer project with Sanofi.



Scientists at QIAGEN's center of excellence in molecular pathway analysis technologies in Maryland are virtual partners in the translational medicine project focusing on liver cancer.

»R&D is no longer just doing physical experiments in the lab. The focus is shifting to information that we are collecting from patients themselves.«

DR. XIAO ZENG

Vice President Genomic Assays and Content Development, QIAGEN

### The way forward is translational

Around the world, leaders in R&D are embracing translational medicine as the way forward – along with collaborations that connect companies and resources. The aim is to speed up the time to develop new medicines – more than 10 years – and improve productivity since the cost of developing a new medicine is estimated at more than \$1.2 billion, according to a Tufts University survey.

"What we are doing here is developing and implementing a new strategy," says Sanofi's Dr. Tao. "Great research occurs not only inside a company, and we need to identify a lot of the exciting science occurring elsewhere. In China, where our mission is to address the diseases of the Asia-Pacific region, we don't have our own lab. Our model is what we call Virtual Discovery, and we work with the best partners worldwide."

Sanofi and QIAGEN are networking with several organizations as part of the collaboration. For example, the Shanghai Clinical Research Center (SCRC) provides a full range of clinical research and translational services – clinical trial management, third-party biobanking services, a central laboratory, data management and regulatory affairs.

QIAGEN provides about 70% of SCRC's test kits, reagents and consumables in biobanking and translational research. Dr. Rongxing Gan, President and CEO of SCRC, says QIAGEN is far more than just a supplier since the organizations have highly complementary expertise. "To succeed in clinical research, we need companies like QIAGEN to support us," Dr. Gan says. "And QIAGEN is winning from our collaborations as well. It is an excellent situation for all parties involved."

The creation of these types of relationships is helping China become a global hub for Pharma R&D

collaborations. The Sanofi-QIAGEN partnership draws upon expertise and capabilities at QIAGEN's Translational Medicine Center in BioBAY as well as QIAGEN's center in Frederick and other organizations around the world.

By combining cutting-edge drug development with advanced molecular technologies, QIAGEN and Sanofi are matching the right treatments with the right patients. Liver cancer patients in China will hopefully be the first to experience the benefits. The point of translational medicine, after all, is to improve the lives of patients.

"R&D is no longer just doing physical experiments in the lab. The focus is shifting to information that we are collecting from patients themselves, and we are working increasingly in a virtual environment," Dr. Zeng says. "Our standardized assays then help to weed out the noise from basic research and quickly convert knowledge into useful clinical benefits for patients. This is how we are contributing and leading the industry in Translational Medicine."



DR. RONGXING GAN  
says Shanghai Clinical  
Research Center and  
collaborators bring  
complementary skills to the  
liver cancer project.

# New tool against an ancient enemy

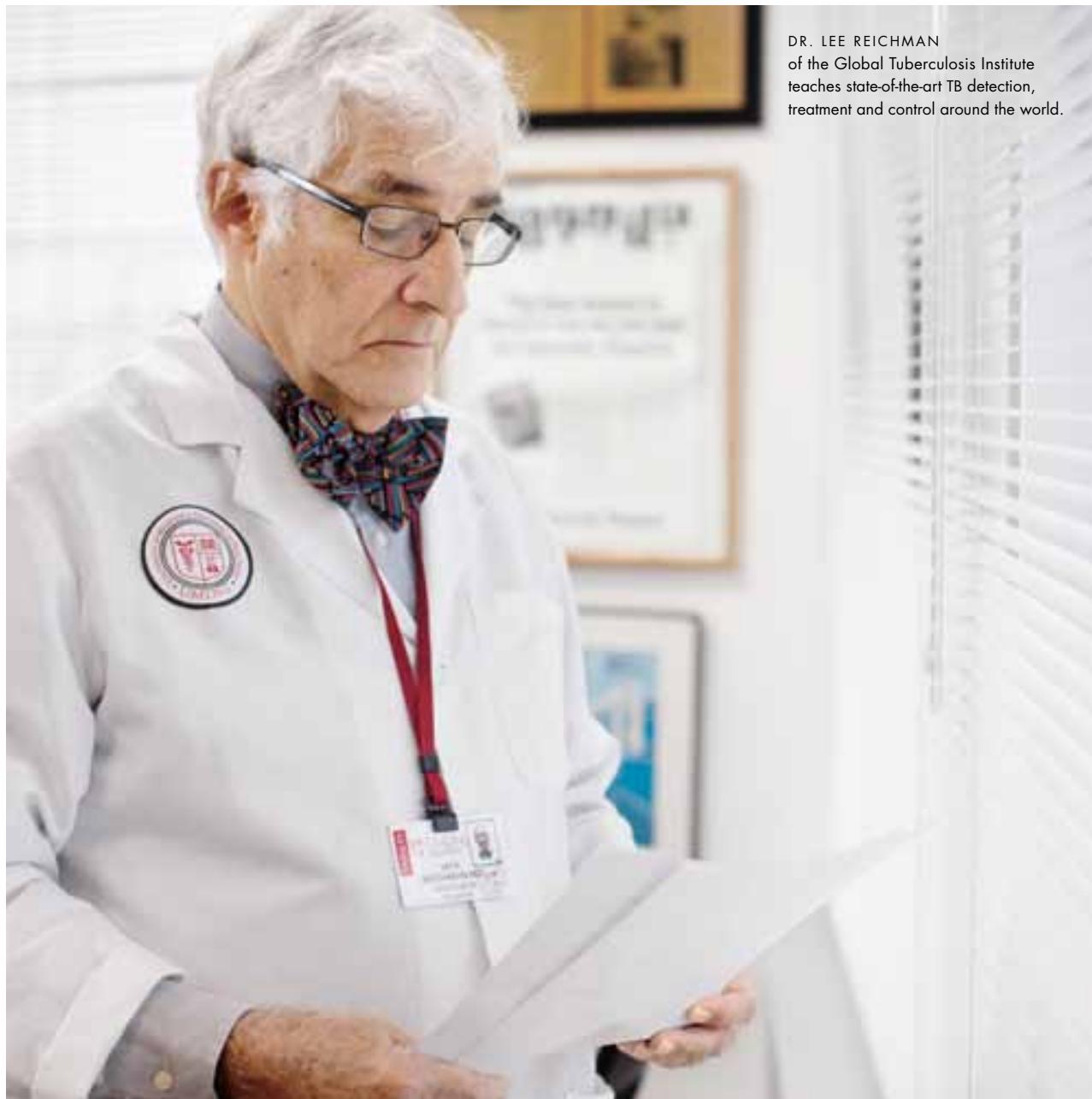
AUTHOR: Richard M. Johnson

PHOTOGRAPHY: Andreas Fechner



DR. AMEE PATRAWALLA  
treats tuberculosis patients, including latent  
TB infections identified by QuantiFERON-TB  
Gold In-Tube, in Newark, New Jersey.





DR. LEE REICHMAN  
of the Global Tuberculosis Institute  
teaches state-of-the-art TB detection,  
treatment and control around the world.

»Tuberculosis is a global disease. Today you can go anywhere in the world in 20 hours. So if you want to control TB anywhere, you have to control it everywhere.«

DR. LEE REICHMAN

Executive Director, Global Tuberculosis Institute

# To protect patients and control the spread of tuberculosis, a world-class TB clinic replaced the antiquated skin test with QIAGEN's innovative QuantiFERON-TB Gold In-Tube.

René, a 45-year-old man from Haiti, became very ill last summer while visiting his brother's family in Newark, New Jersey. He began coughing uncontrollably, losing weight, growing more and more weak.

When relatives took René to a hospital emergency room, doctors quickly recognized the symptoms of tuberculosis (TB), one of the oldest and most stubborn infectious diseases. A chest X-ray showed tell-tale damage from this bacterial infection to his lung tissue. René was sent to the nearby clinic of the Global Tuberculosis Institute, where physicians started him on four high-powered antibiotics. TB is curable but demands a rigorous nine-month course of drug therapy.

At the same time, the TB clinic immediately sought out close contacts of René – seven relatives who share the house in Newark – and brought them in for screening with the most sensitive test available for latent tuberculosis infection, QIAGEN's QuantiFERON-TB Gold (QFT). A sister-in-law, niece and nephew tested positive, placing them at high risk of developing active TB disease. All three went on a shorter three-month antibiotic regimen that kills the bacteria before it can develop into active disease.

René, his name changed to protect his privacy, is overcome by emotion when outsiders ask about his disease. He does not want other Haitians to learn of his illness because in his home country, which has the highest rate of TB in the Americas, the disease strikes fear into people's hearts. René pours

out his fears in Creole, while his sister-in-law speaks for him in English.

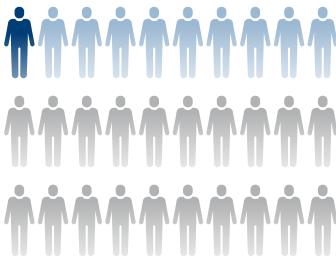
"In Haiti, when somebody gets TB, they often die. It costs a lot of money to get treatment, and most people cannot afford it. René is getting a lot of help here, a lot more than he would back home," says his sister-in-law, who works as a nurse's aide and periodically moves back and forth from Haiti with the family. "Once we found out about his condition, I quickly went to get my kids tested. I knew I needed to act fast to protect them."

## QuantiFERON transforms TB control

Protecting families, co-workers and others at risk from tuberculosis is what QuantiFERON-TB Gold does, and QIAGEN has emerged as a leader in the global effort to control TB.

QuantiFERON-TB Gold is a highly accurate modern method of screening for TB infection, and it has begun to rapidly replace the 105-year-old tuberculin skin test. Though still widely used, the skin test is fraught with shortcomings: subjectivity, a high rate of "false positives," and the need for two patient visits to complete one test.

QuantiFERON-TB Gold avoids those issues and provides an early warning by aiding the detection of TB infection before it becomes an active disease. QIAGEN is expanding market acceptance for this unique technology following the August 2011 acquisition of Cellestis Ltd., the Australian biotech company that developed the QuantiFERON technology.



One-third of the world's population (2 billion) are estimated to have latent TB. Approximately one in 10 of them will develop active TB. As their contacts are infected, TB will spread – unless society implements effective TB detection and control.

Although tuberculosis can be cured, it remains difficult to eradicate. TB still rages in the poor countries of Asia, Africa, Eastern Europe and the Americas, killing more than 1 million people a year. Even in wealthy countries the ancient disease remains a threat for vulnerable groups of people – those who have recently been exposed to active TB or whose immune system is compromised.

"Tuberculosis is a global disease. Today you can go anywhere in the world in 20 hours. So if you want to control TB anywhere, you have to control it everywhere," says Dr. Lee Reichman, Executive Director of the Global Tuberculosis Institute. He travels the world teaching TB detection, treatment and control. At home in Newark, his Institute's clinic provides world-class diagnosis and treatment for TB.

One of the toughest aspects of tuberculosis is that its bacteria can lodge in a person's lungs and stay "latent" (inactive) for months or years. About one-third of the earth's population – 2 billion people – carry the TB bacteria in this latent mode, the World Health Organization says. About one in 10 people with latent infection will someday develop active, contagious TB – often when their immune systems are weak.

QuantiFERON-TB Gold detects latent TB with a novel and highly accurate technology, which enables potentially fatal pathogens to be identified before their DNA or RNA are present in amounts that can be measured with molecular technologies. This is achieved by analyzing blood samples to measure the body's own immune response to any infection

with TB bacteria. Authorities worldwide are embracing QFT to screen people who are particularly susceptible to developing active disease, as well as those who work or live with people who could be endangered if active TB emerges.

#### **Global threat calls for TB screening**

Two decades after the World Health Organization (WHO) declared tuberculosis a "global public health emergency," the disease persists in spite of progress in the availability and quality of care. Around the world, 8.7 million patients developed active TB in 2011 and 1.4 million died – ranking tuberculosis second only to HIV among the deadliest infectious agents worldwide.

Tuberculosis is endemic in many developing countries and thrives amid malnutrition, cramped living conditions and diseases like AIDS that suppress the immune system.

Drug-resistant tuberculosis is a growing problem because patients in low-resource areas often stop therapy before finishing the demanding antibiotic regimen. Nonprofit groups and governments are fighting TB in developing regions by implementing WHO's ambitious strategy for "directly observed therapy" – which means that a healthcare worker must be present for each patient's daily dosing with antibiotics.

In the United States and Western Europe, incidence of active TB is relatively low thanks to a century of TB control programs. Treatment is spearheaded by public health organizations such as the Global

A nurse in the clinic at the Global Tuberculosis Institute draws blood for the highly accurate QuantiFERON-TB Gold In-Tube diagnostic kit.



Tuberculosis Institute's clinic at the New Jersey Medical School in Newark. Protecting latent TB-infected patients from active disease – and preventing contagion – are top priorities in the modern war on TB.

The risk in industrialized markets is highest for specific, identifiable groups – and these are the people most in need of screening with QFT. The first line of containment is to identify and test contacts of active TB patients, who may have infected those around them. People with weakened immune systems – such as HIV-positive, rheumatoid arthritis and chemotherapy patients – are vulnerable to TB infection, whether from recent or past exposure, and can more readily develop the active disease.

Immigrants, international students and travelers, especially involving countries with a high TB burden, are statistically more likely to be infected with the TB bacteria. People living or working in cramped situations – prisoners and staff, military members, some members of other occupations – also are vulnerable.

Healthcare workers themselves are a high-priority target for screening because of the double risk: Nurses and doctors can face on-the-job exposure from patients with undiagnosed active TB, and if they progress to active TB they become a potential threat to other patients.

QIAGEN's outreach strategy for QuantiFERON-TB Gold focuses on reaching these targeted groups through healthcare providers and employers. Dr. Reichman advocates a "screen and treat" approach that can diminish by about 90% the risk of latent TB patients developing active disease.

QIAGEN estimates the need for latent TB testing at 15 million tests per year in the United States and 50 million worldwide. Screening has only begun to address the need.

#### **Tuberculosis goes to a school**

When active TB surfaces in the general community – such as in a crowded workplace or school – Mark Wolman, program manager for TB control at the Institute in Newark, experiences his scariest moments. It may begin with a call to the public health hotline, which rings 10 feet from his desk, that a 17-year-old high school student has arrived in a hospital with signs of active TB.

"If they are contagious, we jump on it," Wolman says. "We go to the hospital and talk with the patient and family about tuberculosis. Even if the disease is not yet confirmed, because bacteriology results can take weeks to come back, we want to make them aware of TB and how it works."



MARK WOLMAN tracks contacts of tuberculosis patients, and those who test positive for latent TB receive preventive treatment.

# 1.4 million

people worldwide die  
each year from TB

Wolman or his colleagues go next to the school – to communicate directly with students, teachers and parents and to develop a list of contacts of the sick student. The TB control officer draws seating charts in each class to see who was close enough to inhale droplets from a cough or sneeze. Students who share several classes or “hang out” with the sick student are more at risk. Teachers also can be vulnerable.

As many as 70 students and staff may be tested in a typical school outbreak. In a workplace, it's often not that many, because workers have a limited number of close contacts. But schools need a lot of outreach, with letters and meetings to inform and motivate all stakeholders.

“Parents become very concerned, so we try to deal with their anxiety,” Wolman says. “At the same time we want to persuade anyone who is a close contact to get tested, and if they test positive to get treated for TB infection. Otherwise, they can walk around with this bacteria and maybe 20 years later something causes the immune system to be weakened – and they get active tuberculosis.”

#### New technology drives out old

For more than a century the tuberculin skin test was the accepted way of screening for TB infection, despite being subjective and difficult to use. Now QIAGEN has launched a market conversion strategy to replace the skin test with the QuantiFERON-TB Gold – more accurate, faster and more cost-effective.

Dr. Masae Kawamura, longtime head of tuberculosis control in San Francisco, joined QIAGEN in 2012 as senior director, medical and scientific

affairs. The reason: QuantiFERON-TB Gold is making a difference.

“During my time as Director and TB controller of San Francisco, QuantiFERON transformed targeted testing and treatment of populations most vulnerable to TB in our city,” Dr. Kawamura says. “We were able to reduce TB rates and nearly eliminate transmission in homeless shelters, while cutting in half the positive rates in our community clinics.

“QuantiFERON provides the big opportunity to wholeheartedly implement U.S. TB-elimination screening guidelines with a test that is better, more believable and more operationally feasible than the skin test.”

The skin test, first used in 1907, involves injecting a small amount of material from TB bacteria under the skin of a patient’s forearm. Two or three days later, the patient is rechecked. A swollen or red bump may be read as “positive” for TB infection, but the interpretation is a judgment call.

QuantiFERON-TB Gold In-Tube, the third-generation QFT kit, starts by taking a sample of a patient’s blood in three vials: two holding specific TB antigens and one “control.” The vials go to a laboratory, which uses a sensitive enzyme-linked immunosorbent assay (ELISA) to measure the response – and to deliver next-day results.

Timing is important in TB screening. Some patients given a skin test do not return for the second visit, so the test is useless. With QFT, only one visit is needed to produce results.



#### LATENT TB

- TB bacteria in the body are walled off
- Person cannot spread TB bacteria to others
- Person does not feel sick
- Chest X-ray usually normal
- Sometimes has to be treated with medicine to prevent active TB



#### ACTIVE TB

- TB bacteria in the body are active and spreading
- Person can spread TB bacteria to others
- Person usually feels sick
- Chest X-ray usually shows damage to lungs
- Always has to be treated with medicine to cure the disease and prevent spread to others

In addition, the skin test is unreliable in many immigrants because it cannot distinguish an immune reaction to TB bacteria from the BCG vaccine, which is widely used in regions with high TB burdens. QFT is accurate regardless of BCG vaccination.

The skin test yields “false positives” in 20% to 40% of patients – identifying them as infected with TB bacteria and leading to costly but unnecessary follow-up care. QFT positive readings are 99% correct.

“I think QuantiFERON should be used on everybody, but some people still do the old tuberculin skin tests,” says Dr. Reichman, whose Institute has been studying and using QuantiFERON for a decade.

“The only healthcare providers who do skin tests now are people who think that it’s cheaper. Actually, QuantiFERON saves money because it is much more specific, so patients who get a ‘positive’ are people who are really infected with the bacillus. With a more accurate test you have fewer cases to work up through visits to the doctor’s office and chest X-rays, both of which are very expensive.”

Already, leading U.S. laboratory chains have adopted QFT in screening for TB infection – converting from the skin test. The Centers for Disease Control has established this class of test as a benchmark for many patients, including BCG-vaccinated persons and those unlikely to return for a second visit.

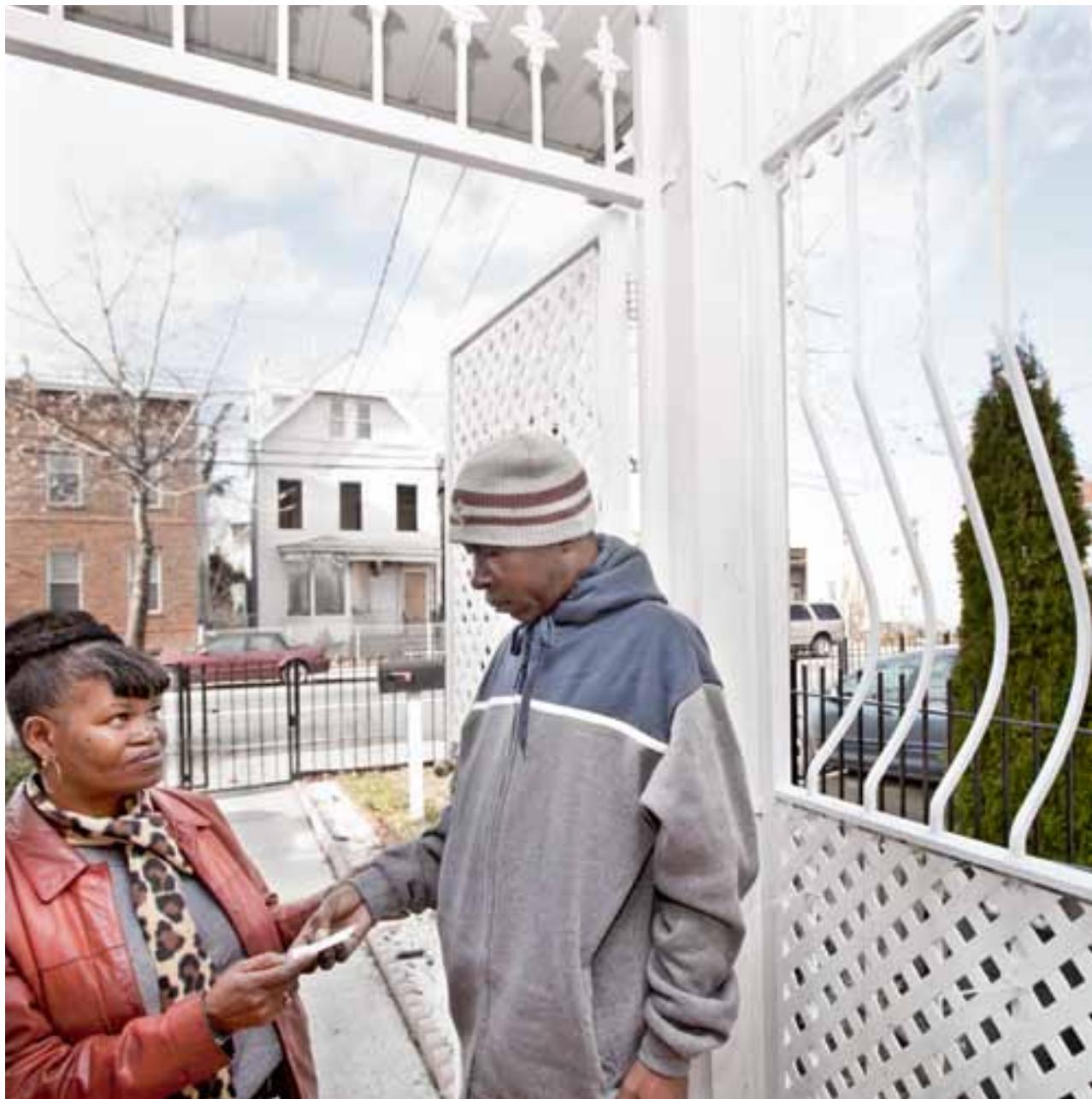
#### Innovation focuses on new applications

QuantiFERON technology is expected to remain a significant growth driver for QIAGEN as anti-TB efforts convert to QFT. The market is far from fully penetrated, and new applications are under investigation.

QuantiFERON-TB Gold, for example, offers promise for screening patients who are candidates for many medications that suppress the immune system. Guidelines for TNF-alpha inhibitors – a widely prescribed class of drugs for rheumatoid arthritis – already require screening for latent TB. Treatments for cancer, HIV / AIDS, diabetes and other diseases may hold similar potential.

Meanwhile, QIAGEN is expanding its footprint in TB control. In 2012, QIAGEN and the Max Planck Institute for Infection Biology launched a collaboration to develop a follow-up test to predict which latent TB patients are likely to progress to active disease – a key question for doctors and patients.

“The ultimate point is to eliminate TB,” says Dr. Reichman. “To do that we need to effectively treat patients with the active disease through directly observed therapy. We need to screen for people with latent TB infection – and treat them so they don’t develop active disease. And we need a tuberculosis vaccine, which is coming, in my view, in five to 10 years. But, globally, we have a long way to go.”



Public health representative Rebecca Stevens delivers tuberculosis medications to a patient in "directly observed therapy."

# 50 million

patients a year need tests  
for latent TB infection

# Quicker results at the point of need

AUTHOR: Richard M. Johnson



A frightening complication in pregnancy, which may threaten the health of mother and baby, can be quickly diagnosed with QIAGEN's AmniSure ROM Test.



# A pregnant woman facing a crisis. A suspected heart attack patient arriving at the hospital. QIAGEN's emerging Point of Need portfolio provides urgently needed answers.

QIAGEN's growing Point of Need portfolio taps into a powerful global trend: the demand for rapid, on-the-spot results from advanced testing technologies in healthcare and other fields.

By investing in innovation, acquiring new products and partnering with other companies, QIAGEN is expanding its platforms and content menu to provide testing in physician offices, emergency care, remote field areas and other settings demanding fast turnaround without the need for access to a laboratory to obtain results.

Working with nearly 100 partners around the world, QIAGEN is now providing "ultra fast" portable ESEQuant platforms to develop diverse applications for the Molecular Diagnostics and Applied Testing markets. In 2012 the ESEQuant Lateral Flow System gained its first regulatory approval in healthcare, from China's State Food and Drug Administration (SFDA), to analyze biomarkers for heart attacks in emergency room settings.

Also in 2012, QIAGEN added a growing diagnostic product to the Point of Need menu by acquiring the developer of the AmniSure ROM Test, a highly accurate assay that diagnoses a widespread complication of pregnancy.

## Point of Need demand grows

In an era of real-time information and mobile communication, the desire to get fast, reliable results from advanced molecular and cellular tests is an emerging trend. Customers are increasingly turning to Point of Need testing in human healthcare, food safety and veterinary diagnostics.

"Testing at the point of need allows healthcare providers to decentralize diagnostics out of the laboratory, into the emergency room or onto the hospital floor and closer to the patient," says Ruben F. Salinas, Vice President & General Manager of QIAGEN's AmniSure International LLC. "The benefits of getting diagnostic results at the patient's bedside include a quicker response and better decision-making, especially when dealing with life-threatening conditions."

Point of Need diagnostics also have special applications in regions lacking laboratory infrastructure. In 2012 QIAGEN joined a collaboration to enhance healthcare in the world's poorest countries, led by the Bill & Melinda Gates Foundation and Grand Challenges Canada. As part of the Point-of-Care Diagnostics Initiative, QIAGEN is creating a portable molecular diagnostics platform for low-resource regions.

Across multiple applications, QIAGEN is building a broad Point of Need portfolio as a growth driver in the Molecular Diagnostics and Applied Testing customer classes.

## Quick answers for urgent concerns

A rapid, simple test from QIAGEN is easing worries for pregnant women who face a frightening complication known as Premature Rupture of Fetal Membranes (PROM), which may threaten the health of both mother and baby.

The suspicion of PROM arises when a woman has unusual amounts of vaginal secretions. If the watery discharge is due to a rupture in the protective amniotic sac, timely treatment with antibiotics and other

Veterinarians in Cameroon use QIAGEN's ESEQuant Tube Scanner, an innovative Point of Need platform, to test livestock for animal diseases.





QIAGEN is exploring many potential applications for its Point of Need technologies in urgent medical situations requiring rapid test results.

# 30%

of all pregnant women need urgent, reliable diagnosis of whether they have premature rupture of their amniotic membranes

measures are needed to avoid serious infections and other complications. Conversely, if a patient is falsely diagnosed with PROM, this can lead to costly and unnecessary hospitalizations, medication and possibly a premature induction of labor.

Up to 30% of pregnant women in the United States are evaluated for PROM during pregnancy and about 10% actually suffer from the condition, yet the methods traditionally used to diagnose it are unreliable.

The easy-to-use AmniSure Test provides a definitive diagnosis of PROM in a few minutes, confirming or ruling out a leak of amniotic fluid without ever leaving the emergency room, birthing center or clinic.

QIAGEN added the AmniSure technology in May 2012 with the acquisition of AmniSure International LLC. In addition to expanding the Point of Need portfolio, the AmniSure product offers selling synergies with QIAGEN's presence in the women's health market as provider of the *digene* HPV Test, the "gold standard" in detection of human papillomavirus (HPV) for the prevention of cervical cancer.

#### **Platforms for Point of Need applications**

Since acquiring ESE GmbH in 2010, QIAGEN has worked with multiple partners to commercialize Point of Need applications on ESE's pioneering optical measurement systems. Two platforms – the ESEQuant Lateral Flow Reader and ESEQuant Tube Scanner – provide rapid test results outside of the laboratory, identifying molecular targets or measuring proteins or small molecules with highest sensitivity.

ESEQuant devices are portable, the size of an office telephone, and battery-operated or plug-in. They can operate in remote rural areas without power or water – or in big-city institutions.

In 2012 QIAGEN announced an agreement with Lepu Medical Technology (Beijing) Co., Ltd., a leading medical device company in China, to provide ESEQuant Lateral Flow systems for use in emergency rooms with Lepu's tests for five biomarkers for the diagnosis of acute myocardial infarction (heart attack).

China's SFDA approved the system with Lepu's cardiac assays, the first regulatory approval of ESEQuant technology in healthcare. Patients suffering heart attacks face the greatest risk of death in the first hour, so the need in emergency rooms is rapid response with appropriate treatments. The lateral flow platform and Lepu's cardiac markers can confirm or rule out a heart attack within minutes, a lifesaving improvement compared to sending out blood samples to a laboratory for analysis.

The cardiac collaboration begins with an initial shipment of 750 ESEQuant instruments to Lepu, which will market the system to hospitals in China under the name LEPU Quant-Gold.

QIAGEN expects continued growth in the future from a deep pipeline of Point of Need tests currently in development, either internally or with commercial partners.

"We are providing our technologies to global players for a wide range of applications," says Dr. Frank Krieg-Schneider, Vice President and Head of Global Strategic Alliances & OEM at QIAGEN. "ESEQuant instruments are being deployed in all walks of life, from drug abuse, to food safety and infectious diseases."

# Creating new standards

AUTHOR: Sara Sharpe

PHOTOGRAPHY: Andreas Fechner



A laboratory technician at Berlin's institut für produktqualität (ifp) prepares lasagne samples for authentication of its ingredients.



# From the farm to the consumer's fork, public health requires vigilance for food safety. QIAGEN is setting new standards with advanced veterinary and food testing technologies.

Throughout the morning, farmers arrive in their 4x4 vehicles in the tidy forecourt of a rural facility near Bakum, a small town in northern Germany, and hurry in to deliver samples from their livestock for testing. The unassuming building is a state-of-the-art veterinary diagnostic center, the Hannover University School of Veterinary Medicine's Center for Epidemiology.

Specializing in diagnosing pigs and poultry, the center is well-known and respected by farmers and authorities for its analytical services – in fact, it also serves as a national certification body for other laboratories involved in monitoring for Salmonella infection. The lab is a valuable resource in an area with one of Europe's largest populations of production animals.

On this day a farmer brings in two pigs showing severe neurological symptoms that are the suspected result of an infection. While these two animals' individual fates are post mortem examination, the farmer hopes the center can tell him exactly what is afflicting the pigs, so that he can protect the rest of his herd with appropriate preventive action.

The head of the center, Dr. Thomas Blaha, Professor of Epidemiology and President of the International Society of Animal Hygiene, says advanced diagnostics play a vital role in veterinary medicine. Among the driving forces are the economic benefits of preventing the spread of disease compared to post mortem testing of herds, the need to reduce misuse of antibiotics in the food chain and concerns about the welfare of animals themselves.

"Good farming practices and biosecurity are essential to ensure animal welfare, food safety, public and environmental health, as well as good economic return, and diagnostics play an increasingly important role," Professor Blaha says. "Animal health and welfare, in particular, are receiving more and more attention in light of new challenges created by changing husbandry practices such as mixing different animals with a varying immune status in larger herds."

Animal health issues not only cause direct livestock losses and compromise animal welfare, but can lead to significant economic loss through diminished performance. The World Organisation for Animal Health (OIE) estimates that diseases in animals reduce global farm production by 20%. Rather than waiting until after a herd is devastated before finding out what killed the animals, farmers are now increasingly seeking early diagnosis to guide specific actions they can take to halt an outbreak of illness.

The well-being of animals is interconnected with the health of humans. Although not all animal diseases are contagious or dangerous to humans, many byproducts from infected animals should not enter the food chain, so they must be detected as early as possible. More than 60% of the 1,400 pathogens known to affect humans are zoonotic and can affect animals and humans. The One Health movement – a strategy for integrating disciplines in healthcare for humans, animals, plants and the environment – is gathering momentum worldwide.

»PCR testing is definitely replacing our classical tests because results can be obtained much faster.«

**ANDREA DÜNGELHOEF**

Center for Epidemiology, Hannover University School of Veterinary Medicine

#### Partners in veterinary diagnostics

QIAGEN has a growing, high-quality veterinary testing portfolio for the detection and monitoring of many animal diseases. In 2012, QIAGEN introduced 20 new veterinary test kits worldwide and saw a double-digit increase in corresponding sales.

"We carry out a wide variety of testing on live and dead animals, including both routine diagnostics and specific research projects. Each year, we examine up to 40,000 samples of all kinds of animal tissue using a wide variety of tests from bacterial cultures to PCR testing," explains Andrea Düngelhoef, a qualified veterinarian and head of the molecular biology lab at the center. "PCR testing, such as that offered by QIAGEN, is definitely replacing our classical tests because results can be obtained much faster – 24 hours, as opposed to one to two weeks. PCR testing also allows us to explore the pathogen, even if it is dead, which is a major advantage."

Professor Blaha sees diagnostics as key to further improving animal health. "With more knowledge about an individual animal's immunity, explored via sensitive diagnostics, we could maintain better herd health," he says. "And we can tackle major challenges, such as the overuse of broad-spectrum antibiotics for unspecified health conditions without proper diagnostic determination of the exact cause – and the ultimate development of antibiotic resistance in animals and humans. More frequent and sensitive diagnostic testing would identify the specific animal disease and allow appropriate treatment with a specific antibiotic."



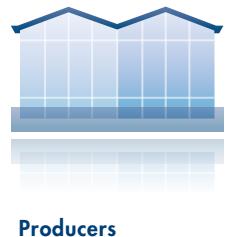
Scientist Andrea Düngelhoef loads samples into a QIAcube system for automated DNA extraction at the Center for Epidemiology near Bakum, Germany

#### From farm to factory

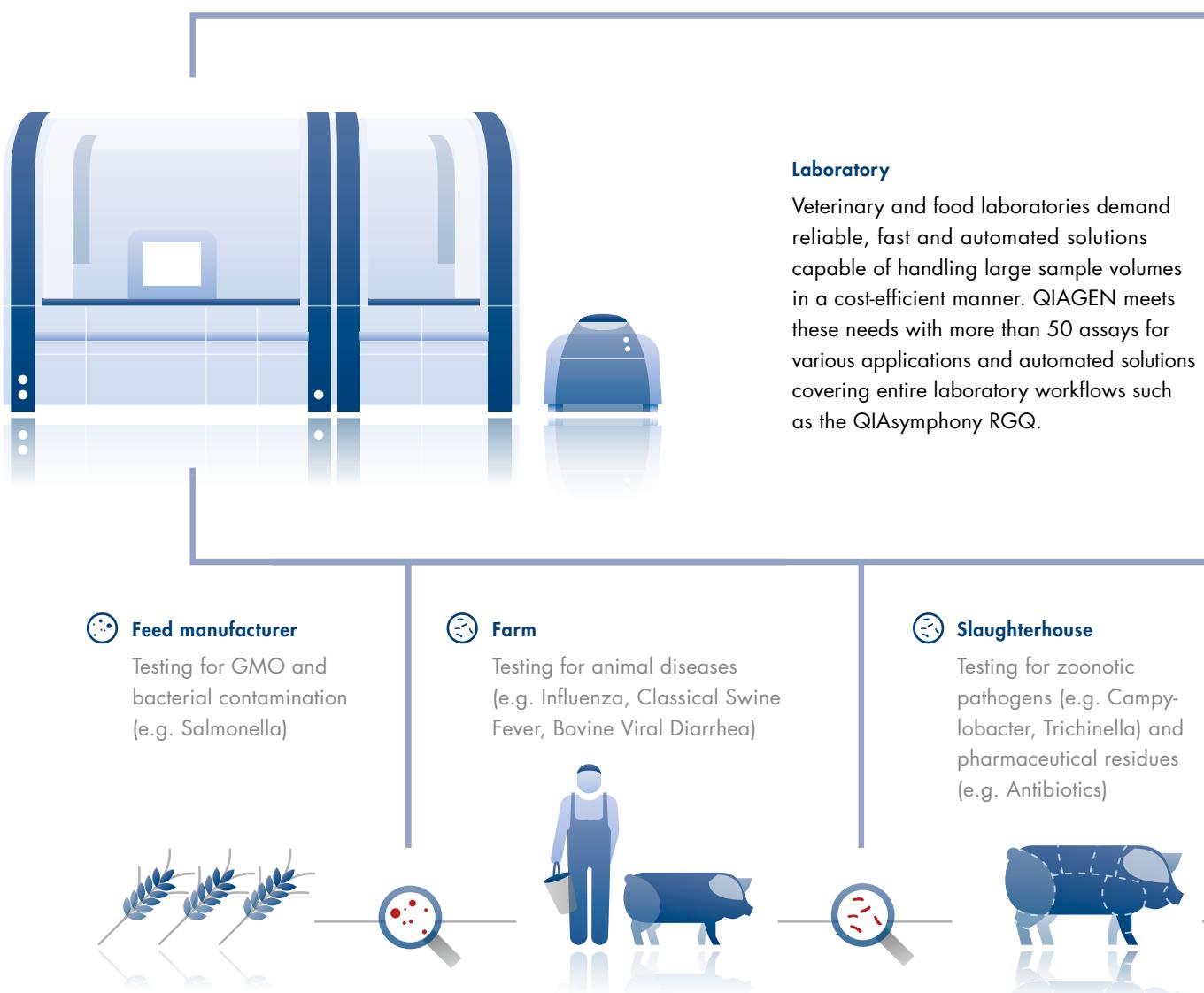
Ensuring the safety of our food throughout its production, processing and delivery is essential. Food-borne diseases cause significant numbers of deaths and widespread illness globally. Severe outbreaks can spread rapidly in the globalized food industry, threatening lives, disrupting food supply and causing severe economic loss. Widely publicized incidents are a reminder of the fundamental importance of food safety. Reliable monitoring needs to be implemented through the entire chain to prevent and control contamination, protect consumers and other stakeholders, and ensure adequate standards of animal health and welfare.

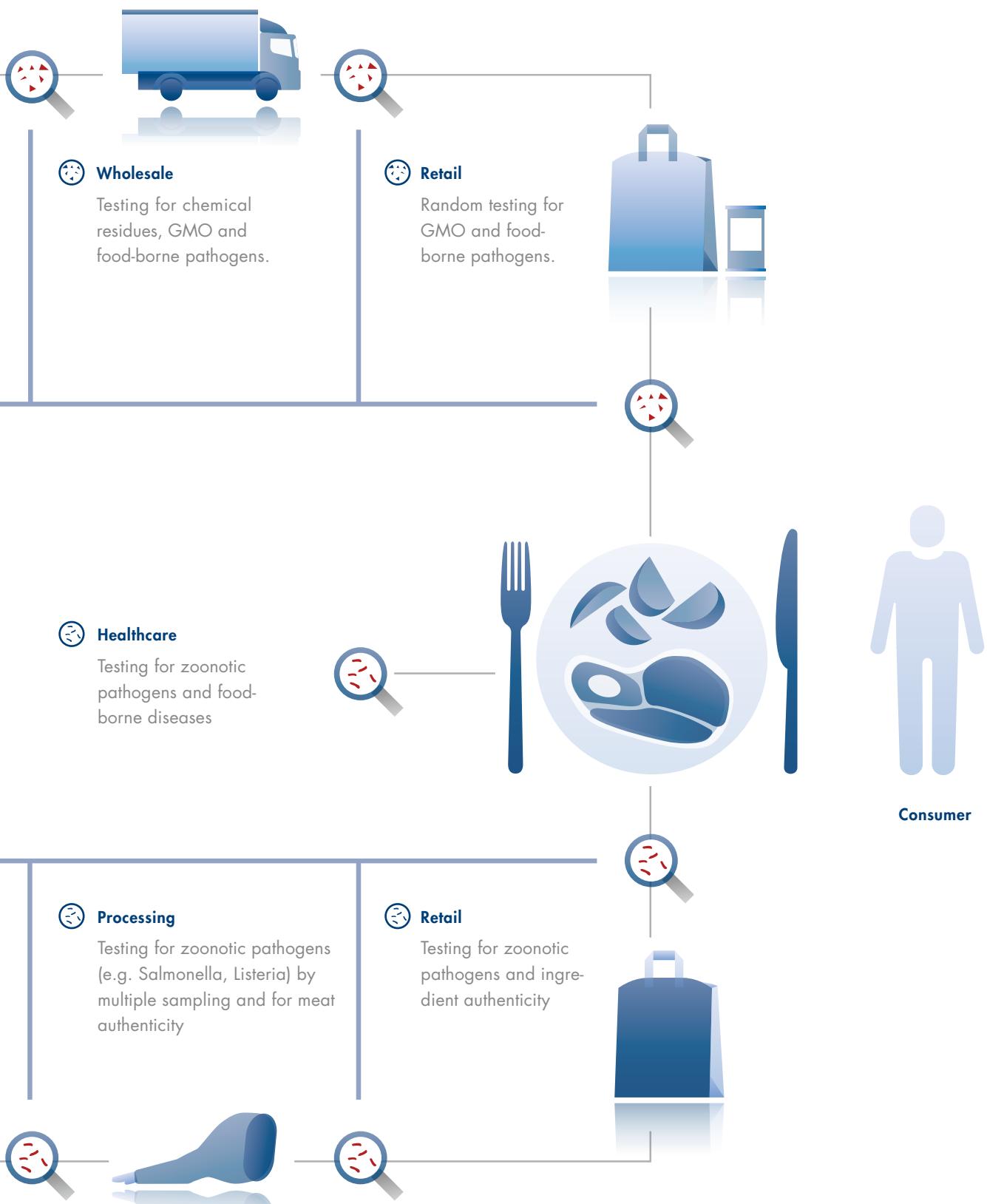
In recent decades, significant and continual progress has been made, including many changes in food safety measures. Improvements have been driven mainly by stakeholders within the long and

As the supply chain for our food supplies has grown more complex and more global, QIAGEN's technologies help to protect the health of animals and consumers, as well as the economic vitality of food producers.



Producers







Samples await analysis at Hannover University's state-of-the-art veterinary lab, which helps local farmers to maintain the health of their animal herds.

# 963,044,187

pigs produced worldwide in 2011

complex supply chain, such as food manufacturers and retail chains, and spurred by developments in science, technology and regulation.

Had the two pigs that appeared in the veterinary diagnostic center been healthy, they might have been sold to a company like Tönnies, a leading global producer of pork and beef products headquartered in Rheda-Wiedenbrück, Germany, not far from the veterinary diagnostic center.

Tönnies is a leading food-processing company that creates a significant number of meat products every day from pigs and cattle, and exports its products all over the world through its network of 25 international offices and 8,000 employees. It has a holistic view on animal health and food safety and is driven to achieve safety, animal health and welfare standards that exceed industry and market requirements, enabling the firm to achieve a premium for its products on the national and international markets. The layout of all production facilities strictly follows the rules of "Inline Production" – that is, slaughtering, deboning, processing and packing is managed at one place within a continuous chain of appropriate cooling and precise quality management.

To ensure safety throughout the meat preparation process, Tönnies implements a large number of precautions, including extensive diagnostic testing, as part of everyday routines. These are essential because many major safety and quality assurance systems have been put in place, for example, the QS-system and International Food Standard (IFS). Operations at Tönnies are carried out under constant monitoring by their own teams and by external, independent bodies.

In the future, Tönnies hopes for even more transparency in production and processing industries with regard to animal health, possibly requiring even more testing at the farm level, to further improve food safety and quality, animal health and welfare. To this end, the company has implemented a real-time data processing system which enables them to continuously monitor the quality of the animals received and provide feedback to farmers, who can then benchmark their performance and implement continuous improvement strategies.

"We would like to have a lot more information from our suppliers about their herd health, such as whether a herd is healthy, or if certain animals have received any treatment," explains Josef Tillmann, General Manager at Tönnies. "After all, we ideally want to ensure that the animal is healthy when it comes to us and do not want to have to carry out additional tests. We have achieved this already with Salmonella monitoring. We were one of the first companies to implement this across the board. Today we have a really accurate overview of the Salmonella status of a farmer's herd."

Diagnostic technology and partnerships with innovative companies, such as QIAGEN, play an important role in achieving safety targets. QIAGEN's food testing portfolio is based on real-time PCR technology and offers fast, highly sensitive and affordable tests that are validated and accredited by many leading food quality authorities.

"We are glad to have new techniques such as real-time PCR at our disposal for monitoring microbes because they enable us to detect germs at a much lower level – actually at a point that simply cannot be improved further – and speed our diagnostic

procedures significantly. In the past, testing for *Salmonella* took at least three days. Now, we can obtain results with PCR in 20 hours. Without any doubt, this has marked a major step forward for us in terms of our processes," Tillman says.

QIAGEN's engagement in food safety testing is relatively recent, but the Company has invested significantly over many years to expand and transfer its expertise from other industries to the sector. For food safety testing during processing and distribution, QIAGEN already offers more than 30 real-time PCR tests and is continually expanding the range of tools available for highly specific and sensitive food safety tests. The latest addition to QIAGEN's portfolio is a highly specific and sensitive test for detection of horse meat in food products, whose development was accelerated in the wake of the European food safety scandal involving convenience food. Sales of QIAGEN's food testing portfolio rose at a strong double-digit rate in 2012.

#### New challenges for laboratories

The challenge of ensuring food safety is global and growing. The world's population is predicted to exceed nine billion by 2050, putting extreme demand on food supplies. The need for animal protein alone is expected to double, and this enormous increase will bring expanding efforts to improve the quantity and quality of livestock production, its health and welfare. QIAGEN is committed to providing solutions in food safety and animal health.

With the burgeoning food industry facing increases in monitoring requirements, many food safety laboratories face higher volumes and added time pressures. Towards improving workflows, the QIAAsymphony RGQ modular platform provides opportunities to automate laboratory procedures. In February 2012, QIAGEN launched a novel kit for

automated DNA isolation from food samples on this platform to create new opportunities for food safety testing. By the end of 2012, the installed base of QIAAsymphony systems has grown to more than 750 units, with Applied Testing laboratories accounting for the majority of the 30% of placements achieved in the Life Sciences business area.

The institut für produktqualität (Institute for Product Quality, ifp), is a large independent laboratory for food, feed and pharma analysis in Berlin, Germany. The institute is involved in numerous research projects and is the sort of establishment that might be commissioned to carry out routine testing to ensure the safety of products from processing companies, such as Tönnies.

"No other company offers an equivalent 'one-stop shop' in PCR testing for food. QIAGEN is setting new standards in food testing worldwide," says Dr. Wolfgang Weber, head of ifp. "The PCR tests from QIAGEN are superior to traditional methods that we have used in the past at our institute, saving us a great deal of time with results available within 20-24 hours. They are also more reliable, which provides additional safety in food quality testing. By extrapolating the same basic technology, QIAGEN has created a wide range of possibilities for us to test for a whole range of pathogens, and even subtypes of each pathogen, animal diseases and Genetically Modified Organisms (GMOs)."

"With our company growing rapidly, the QIAAsymphony is the perfect tool to automate testing, increase the turnover of samples that we can examine significantly and ensure even safer results through automation," Dr. Weber continues. "With the assurance of enhanced performance and accuracy provided by QIAGEN's machine, I literally sleep better at night!"

## ANMELDUNG



»Good farming practices and biosecurity are essential to ensure animal welfare, food safety, public and environmental health, as well as good economic return.«

PROF. THOMAS BLAHA

Center for Epidemiology, Hannover University

# Emerging markets driving growth



AUTHOR: Richard M. Johnson

An aerial photograph of the city of São Paulo, Brazil. The foreground is filled with a dense cluster of buildings, mostly high-rise residential and office towers, showing a variety of architectural styles and colors. In the background, the city extends towards a range of low mountains. The sky above is filled with large, white, billowing cumulus clouds, creating a dramatic contrast with the urban landscape.

São Paulo, Brazil, with 20 million people,  
exemplifies modern cities in emerging markets,  
where growing middle classes drive demand.

To share in emerging markets' rapid growth, QIAGEN focuses on the specific needs of local research communities and the growing middle-class – and strategically builds a presence in each country.

Around the world QIAGEN is enhancing performance through a strategic initiative to expand its geographic presence – especially in high-growth emerging markets. The Company's top seven emerging markets – Brazil, China, India, Mexico, Russia, South Korea and Turkey – contributed 12% of net sales in 2012 and continued to grow at a double-digit rate.

The ongoing expansion of QIAGEN's presence in emerging growth markets is about more than participating in their economic momentum. Societal changes in developing countries are driving growth in demand for advanced diagnostics in healthcare and molecular technologies in life sciences.

"These economies are growing so much that poor people are increasingly moving into the middle class. In Brazil, for example, 40 million people shifted from poverty into the middle class between 2003 and 2011. So people who in the past were not in a position to pay for healthcare now can afford it, which drives up the level of diagnosis and treatment," says Sandra Reiser, QIAGEN's Vice President for Latin America.

"Our Life Sciences business is benefiting from public investment in research, because governments in emerging markets know that if you want to become a developed country you must have budgets to support technology. There is a lot of interest in technologies for research."

Reiser grew up in Brazil, studied biomedical science in São Paulo, progressed through sales and management roles in international healthcare companies and joined QIAGEN five years ago. So she

has had a close-up view of the emergence of markets like Brazil.

"We have three times the revenue now in Latin America that we had in 2008," Reiser says. "The teams we have created are motivated, selling a whole range of products, and we continue to expand our position."

#### **Emerging markets defy stereotypes**

Latin America and other developing regions are a study in contrasts. For example, the business environment within Brazil, Latin America's largest market with 190 million people, varies widely from the megacities along its southern coast to the rainforests of the Amazon River Basin in the north.

"Greater São Paulo has 20 million people, and it's modern and globally connected. Our hospitals are advanced, and the laboratories are centralized and highly automated," Reiser says. "One of our major customers in Brazil, DASA S.A., is the fourth-largest laboratory in the world – and it is equipped with QIAAsymphony instruments. We are working at the forefront of technology in this country."

QIAGEN in Brazil is providing companion diagnostics for the treatment of cancer, tests for HIV and other diseases, and the "gold standard" *digene* HPV Test to screen women for human papillomavirus (HPV), the primary cause of cervical cancer. The Company also has close relationships with academic and industry scientists using state-of-the-art molecular testing for research.

The undeveloped areas of the Amazon, on the other hand, have little infrastructure – but QIAGEN is

engaged in these regions as well. For example, a new high-performance molecular diagnostic from QIAGEN, the *careHPV* Test, is the world's only HPV assay designed specifically for low-resource areas. The assay is easy to administer, needs no laboratory or refrigeration, and runs on instruments that are well-suited to rural travel. Medical teams visit remote villages along the Amazon and its tributaries – by boat or by pickup truck – to screen women with *careHPV* and provide urgently needed treatment for those at risk for cervical cancer.

"Lives are being saved with this test. In big cities with fully equipped laboratories the *digene* HPV Test is ideal, but in the Amazon region the *careHPV* system is the perfect match. By meeting this need QIAGEN has a great entrée to emerging markets," Reiser says.

#### **Strategy builds QIAGEN presence**

A long-term strategic commitment to invest in rapidly growing markets is paying off for QIAGEN. Ten years ago the Company had a direct sales presence in only nine countries. Today, QIAGEN is active in more than 35 markets.

QIAGEN's strategy for emerging markets follows a dynamic pattern. The Company starts by targeting attractive markets based on size, growth, and funding of healthcare and life sciences. Typically QIAGEN names one or more exclusive distributors to begin selling products and building relationships.

Reiser says the door-opener may be a diagnostic assay targeting an infectious disease such as Tuberculosis, HPV, dengue or other pathogens that are endemic to the country. Or QIAGEN may gain a

foothold through life science researchers, who are likely to know the global reputation of its technologies.

As the business takes hold QIAGEN hires its own sales and service people, experienced in the specific markets. When the scale and growth potential justify further investment, QIAGEN will establish a direct presence by opening a local subsidiary or acquiring one or more companies in the country.

The final stage is to increase market penetration over time through partnerships, new products and regulatory approvals.

#### **Expansion builds on success in China**

In China, QIAGEN's sales have grown rapidly since establishing a direct presence in 2006 – its first emerging market. In 2012 China contributed more than 5% of total sales, with approximately 400 employees supporting commercial, R&D and manufacturing operations.

QIAGEN continues to increase market penetration in China, driving the success of instrument platforms including the QIAxSymphony system and expanding the content menu to add applications in healthcare and life sciences.

In 2012 the State Food and Drug Administration (SFDA) approved QIAxSymphony SP for automated sample preparation and QIAxSymphony AS for assay setup workflows. With the 2010 SFDA clearance of the Rotor-Gene Q real-time PCR thermocycler, QIAGEN now offers customers in China the full QIAxSymphony RGQ modular system.



»People who in the past were not in a position to pay for healthcare now can afford it, which drives up the level of diagnosis and treatment.«

SANDRA REISER

Vice President Latin America, QIAGEN



+ 20%

#### **QIAGEN's top emerging markets**

Sales grew more than 20% in these seven markets in 2012, excluding a major product tender in 2011

In 2012 QIAGEN also achieved Chinese regulatory approval for the *careHPV* Test. Commercial launch of the *careHPV* Test has begun in a large segment of the Chinese market that lacks the access to the level of laboratory infrastructure enjoyed by top-tier hospitals already using the *digene* HPV Test.

Partnering with Chinese companies and research institutes multiplies QIAGEN's presence. Under a 2012 agreement, for example, QIAGEN will supply Lepu Medical Technology (Beijing) Co., Ltd., an initial 750 ESEQuant Lateral Flow Systems for use in emergency rooms. The platform will run Lepu's tests for a set of novel markers that detect myocardial infarction (heart attack). The SFDA granted the ESEQuant lateral flow technology its first approval globally for an application in human healthcare.

Also in 2012, QIAGEN launched a joint venture with the BioBay life sciences campus – home to more than 200 domestic and foreign companies in clinical research, drug discovery and related fields. The partnership already has begun to yield collaborative relationships.

#### **Building relationships with the best**

The human side also is critical to success in emerging markets: QIAGEN seeks the best people, with "on the ground" experience, to build relationships in countries and across regions.

For example, employees of Buenos Aires-based Tecnolab, an exclusive distributor in Argentina, take part in online training and webinars on QIAGEN products, in addition to frequent calls at the management level. "Communication between Tecnolab and QIAGEN has been very good. This helps in solving problems and making decisions," says Martin Hunter, commercial manager for Tecnolab.

Gerardo Montenegro, general manager of Capris Medica, a Central American distributor based in Costa Rica, says QIAGEN brings experts on cancer diagnostics and other topics into his markets and keeps him up to date with emails and conference calls. "Something I really like in this relationship is that we are in constant contact with QIAGEN," he says. "We work with 12 to 15 different companies, and with no other company do we have anything close to the level of communication we have with QIAGEN."

The emphasis on communication is strategic. "How we set up these relationships is the key to our success," Reiser says. "We put distributors together with QIAGEN's team, bring them into sales meetings and training, to help them know that they are part of QIAGEN – an extension of QIAGEN. We develop customer relationships alongside our distributors."



## 2012 REVIEW

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# THE EXECUTIVE COMMITTEE



**PEER M. SCHATZ**

**Chief Executive Officer  
Managing Director**

Joined QIAGEN in 1993 as Chief Financial Officer and was appointed a Managing Director in 1998 and CEO in January 2004. Mr. Schatz was previously a partner in a private management buyout group in Switzerland and worked in finance and systems positions at Sandoz and Computerland AG, as well as in leadership positions at various startup companies in Europe and the U.S. He graduated from the University of St. Gallen, Switzerland, and obtained an MBA in Finance from the University of Chicago. Through January 2012, he served as a member of the German Corporate Governance Commission. He is a board member of the U.S. industry associations AdvaMedDx and ALSSA. He is also chairman of the Board of Directors of QIAGEN Marseille (formerly Ipsogen S.A.).



**ROLAND SACKERS**

**Chief Financial Officer  
Managing Director**

Joined QIAGEN in 1999 as Vice President Finance and has been Chief Financial Officer since 2004. In 2006, Mr. Sackers became a member of the Managing Board. Between 1995 and 1999, he served as an auditor with Arthur Andersen Wirtschaftsprüfungsgesellschaft Steuerberatungsgesellschaft. Mr. Sackers earned his Diplom-Kaufmann from the Westfälische Wilhelms-Universität Münster, Germany, after studying business administration. Mr. Sackers is a board member of the industry association BIO Deutschland. He is also a non-executive director and chair of the audit committee of Immunodiagnostic Systems Holding (IDS), a publicly listed producer of immunological tests for research and diagnostic applications in the United Kingdom, as well as member of the board of directors and head of the audit committee of QIAGEN Marseille (formerly Ipsogen S.A.).



**DR. DIETRICH HAUFFE**

**Senior Vice President,  
Life Sciences Business Area**

Joined QIAGEN in 2010 as Vice President Marketing, Applied Testing, was promoted to Vice President Marketing, Life Sciences, in 2011 and to Senior Vice President, Life Sciences Business Area, in 2012. Dr. Hauffe entered the industry in 1993 as a product manager with Dionex and held positions of increasing responsibility. From 1997 to 2000 he was a senior product manager in automation for QIAGEN. He returned to Dionex as General Manager for Germany and in 2006 was appointed Vice President Global Marketing and Business Development for Dionex in Sunnyvale, California. He holds a degree in Genetics / Biochemistry from the University of Cologne and a Ph.D. from the Max-Planck-Institute of Plant Breeding, Cologne. He did postdoctoral work at the University of British Columbia in Vancouver, Canada, and taught at the University of Freiburg from 1991 to 1993.



**DOUGLAS LIU**

**Senior Vice President,  
Global Operations**

Joined QIAGEN in 2005 as Vice President Global Operations. He heads Manufacturing, Supply Chain Management, Quality Assurance, Quality Control and Regulatory and Clinical Affairs at QIAGEN. Mr. Liu has thirty years of experience in the life sciences industry and previously worked at Bayer Healthcare, Chiron, Abbott Labs and Washington University. He has worked in the United States and Europe with leadership roles in R&D, Manufacturing, Strategic Planning and Program Management. Mr. Liu has an MBA from Boston University and a BS from the University of Illinois, Urbana. He is a member of several non-profit boards including BioHealth Innovation, Inc. and MBDC, which are public private partnerships focusing on developing the life science industry.



**DR. HELGE LUBENOW**

**Senior Vice President,  
Molecular Diagnostics Business Area**

Joined QIAGEN in 1997 as a scientist in the instruments division and held progressively more senior management positions in Research and Development and Marketing. From 2008 until 2010 Dr. Lubenow was based in Australia and served as Vice President Operations Automated Systems, leading the integration and further development of QIAGEN's real-time PCR platform, an integral part of the revolutionary QIAxSymphony RGQ system. In 2011 she was appointed Vice President Molecular Diagnostics Business, and in 2012 she was named Senior Vice President to lead the Molecular Diagnostics Business Area. Dr. Lubenow graduated with a degree in Molecular Biology from the University of Giessen, Germany, and obtained her Ph.D. in Genetics from the University of Cologne, Germany.



**DR. ULRICH SCHRIEK**

**Senior Vice President,  
Corporate Business Development**

Joined QIAGEN in 1997 and was appointed Vice President Corporate Business Development in 2000. Dr. Schriek previously held sales and marketing positions at Pharmacia Biotech. He earned a degree in Biology and obtained his Ph.D. in Biochemistry from the Ruhr University in Bochum, Germany. Dr. Schriek is a member of various industry panels and organizations, including the World Economic Forum Technology Pioneers Selection Committee and the Nanobiotechnology Initiative started by the German Federal Ministry of Education and Research.



**DR. THOMAS SCHWEINS**

**Senior Vice President,  
Human Resources, Strategy & Marketing Services**

Joined QIAGEN in 2004 as Vice President Corporate Strategy and was appointed Vice President Marketing & Strategy in 2005. In late 2011, Dr. Schweins also assumed responsibility for Human Resources. Dr. Schweins came to QIAGEN from The Boston Consulting Group. He previously worked as Technology Manager, and later as an Assistant to the Management Board, at Hoechst /Aventis. Dr. Schweins earned an M.Sc. degree in biochemistry from the University of Hanover. He obtained his Ph.D. at the Max Planck Society and received an M.Sc. from the University of Southern California in Los Angeles, where he studied business administration and chemistry.



**BERND UDER**

**Managing Director,  
Senior Vice President, Global Commercial Operations (until December 31, 2012)**

Joined QIAGEN in 2001 as Vice President Sales and Marketing and was appointed a Managing Director and Senior Vice President Sales and Marketing in 2004. Mr. Uder became Senior Vice President Global Sales in 2005 following a restructuring of the sales and marketing organization. He retired at the end of 2012 from his Managing Director and Senior Vice President Global Commercial Operations position. He continues to work with QIAGEN in an advisory role. During his career at QIAGEN, Mr. Uder led the global transformation of the sales organization through a multi-channel strategy targeting the four customer classes and supported a six-fold increase in sales since 2001. Before joining QIAGEN, he served as Vice President European Biolab Sales & Marketing with Pharmacia and Vice President Global e.business with Amersham Pharmacia Biotech.



**BENEDIKT VON BRAUNMÜHL**

**Senior Vice President,  
Global Commercial Operations (effective January 1, 2013)**

Joined QIAGEN in 2008 as Vice President Latin America and became Director Corporate Business Development and Interim General Manager at QIAGEN Italy in 2009. In 2010 he was appointed Vice President Emerging Regions and Second Channels. He was named Senior Vice President to lead Global Commercial Operations beginning in 2013. Mr. von Braunmühl started his career at AstaMedica and has held various marketing and sales positions in the healthcare industry as well as in investment banking. He holds a Bachelor Degree in Business Administration from the Graduate School of Business Administration in Zurich, Switzerland.

# COMMON SHARES

QIAGEN was one of the best-performing shares in 2012 among companies in the molecular diagnostics and life science tools industry sector, rebounding after falling under pressure in 2011 amid global economic turbulence. During 2012, QIAGEN made significant progress on initiatives to drive innovation and growth despite a challenging macro environment. Our senior executives and Investor Relations team communicate proactively and openly with the financial community.

## Market Environment

Equity markets around the world performed well in 2012, reaching levels not seen in a few years despite concerns about macroeconomic trends in Europe and the U.S. In the U.S., the benchmark S&P 500 index gained 13%, and in Europe most stocks rebounded from their 2011 lows sparked by the Greek debt crisis. The DJ STOXX 600, which represents the 600 largest companies in this region by market capitalization, rose 14%, while Germany's DAX index of the 30 largest companies in this country advanced 30%.

The molecular diagnostics and life sciences tools segment continued to be affected by key end-market challenges, such as restrained R&D investment among pharmaceutical companies and austerity in government budgets in certain parts of Europe and the U.S., as well as continued high unemployment in the U.S., which dampens patient utilization of physician services and diagnostic tests.

Amid a challenging macro environment, QIAGEN exceeded its full-year 2012 sales and adjusted earnings targets, and made significant progress on initiatives to drive innovation and growth, which fueled demand for QIAGEN's products across all customer classes and regions. These initiatives – designed to improve efficiency and effectiveness – involved reallocating resources with the goals of improving profitability while also enhancing shareholder value and maintaining financial flexibility.

## Listings in the U.S. and Europe

QIAGEN's common shares have been registered and traded in the United States since 1996 on the NASDAQ Global Select Market (NASDAQ National Market prior to July 2006) and in Germany since 1997 on the Frankfurt Stock Exchange (and the Prime Standard segment since its launch in 2003). Dual listing on NASDAQ and the Frankfurt Stock Exchange provides advantages for QIAGEN, our shareholders and

### United States

Market	NASDAQ
Segment	NASDAQ Global Select Market
Ticker	QGEN
ISIN	NL0000240000

### Germany

Market	Frankfurt Stock Exchange
Segment	Prime Standard
Ticker	QIA
WKN	901626

### Capitalization Dec. 31, 2012

Market capitalization	\$ 4.26 billion
Shares outstanding	234,543,793
Free float	97%

employees since dual listing enlarges the potential market opportunity and increases liquidity for our shares. Unlike American Depository Receipts (ADRs), QIAGEN's shares provide equal corporate rights for all shareholders and can be traded on either exchange, in U.S. dollars or euros.

### Share Price and Liquidity

QIAGEN's common share price rose significantly in 2012, ending the year at \$18.15 (+31%) on NASDAQ and at €13.75 (+29%) on the Frankfurt Stock Exchange. At the same time, QIAGEN's common shares provided high liquidity during 2012, with an average daily trading volume of approximately 1.5 million shares (1.0 million on NASDAQ and 0.5 million on the Frankfurt Stock Exchange (XETRA) and other German exchanges). The average daily trading volume for QIAGEN shares was lower in 2012 compared to 2011, as were the overall equity market volumes in both the U.S. and

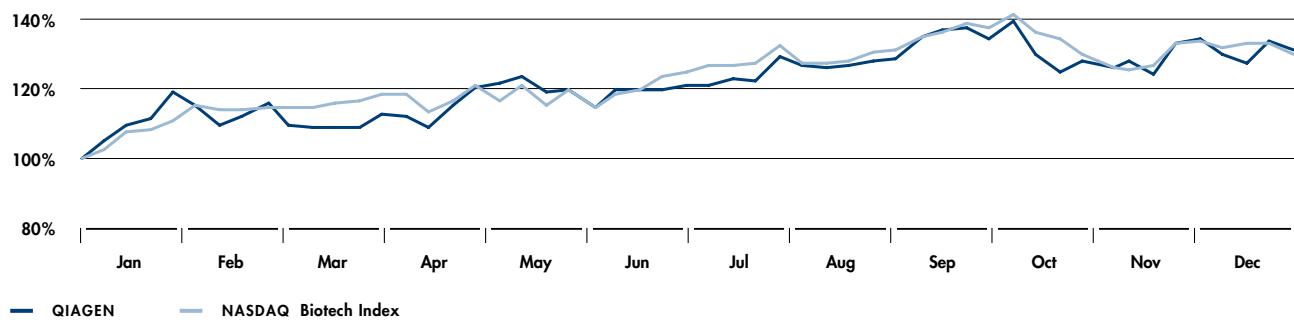
Germany. As of December 31, 2012, the free float, which affects weighting of QIAGEN shares in various indexes, was approximately 97%.

### Index Membership

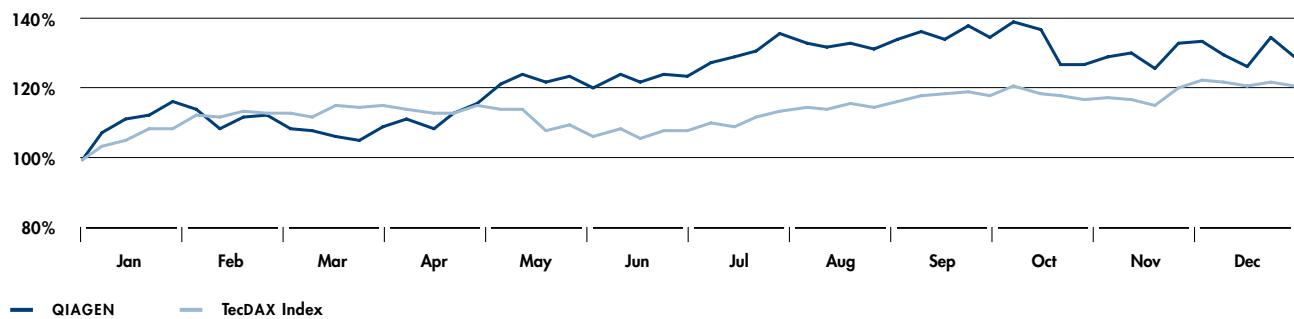
QIAGEN is one of the largest constituents of Germany's TecDAX, a stock index that tracks the 30 largest German companies from the technology sector not included in the benchmark DAX index. As of December 31, 2012, QIAGEN held the No. 1 position among the TecDAX constituents based on market capitalization and trading volume.

In June 2011, QIAGEN was added to the U.S. large-cap Russell 1000 and broad-market Russell 3000 indexes. The Russell 3000 index measures performance of the 3,000 largest companies in the U.S. The Russell 1000 index is a subset of the Russell 3000 index and includes approximately 1,000

#### QIAGEN Share Price Development – NASDAQ 2012



#### QIAGEN Share Price Development – Frankfurt Stock Exchange (XETRA) 2012



of the largest securities based on a combination of their market capitalization and current index membership.

Furthermore, QIAGEN shares are included in other U.S. and European stock market indexes.

### Shareholder Structure

QIAGEN has a truly global investor base comprised of more than 300 identified institutional investors. Approximately 53% of QIAGEN identifiable shares are held in North America and approximately 38% in Europe. BlackRock, Inc., United States, owns approximately 6.0%<sup>(1)</sup> of common shares, as of December 31, 2012, or approximately 14,198,775<sup>(2)</sup> shares. QIAGEN's shareholder base has undergone a transition in recent years from significant holdings by "Growth" style investors toward investors with a "Growth at a Reasonable Price" (GARP) or "Value" orientation. Members of the Managing Board and the Supervisory Board in total held approximately 3.4% of QIAGEN's outstanding common shares at the end of 2012.

### Annual Shareholders' Meeting

At the 2012 Annual Shareholders' Meeting, shareholders voted in favor of all resolutions proposed by the Board of Directors, and in many cases with majorities above 95% of shares present at the meeting. Shareholders present or represented at the meeting held on June 27, 2012, in Venlo, the

Netherlands, held approximately 129.2 million shares, or 54.8% of the approximately 235.6 million issued and outstanding common shares of QIAGEN as of the record date for the meeting. Details of attendance and voting results from our Annual Shareholders' Meeting are available at [www.qiagen.com](http://www.qiagen.com).

### Investor Relations and Transparency

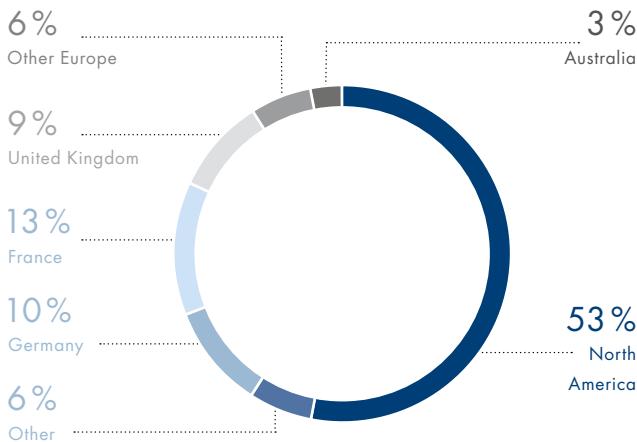
QIAGEN is committed to offering shareholders, analysts and communities around the world transparent, comprehensive and readily accessible information on our strategies, performance and prospects.

In 2012, these efforts to address the needs of the financial community were recognized in the annual Thomson Reuters Extel Awards, with QIAGEN ranking among the top 3 European medtech / biotechnology companies. QIAGEN also ranked among the top 3 for IR Professional among all TecDAX companies in 2012 by DIRK, the association for Investor Relations in Germany.

<sup>1</sup> The percentage ownership was calculated based on 236,486,584 Common Shares outstanding as of December 31, 2012.

<sup>2</sup> BlackRock, Inc., has sole voting power and sole dispositive power over all 14,198,775 shares. This information is based solely on the Schedule 13G filed by BlackRock, Inc. with the Securities and Exchange Commission on February 5, 2013, which reported ownership as of December 31, 2012.

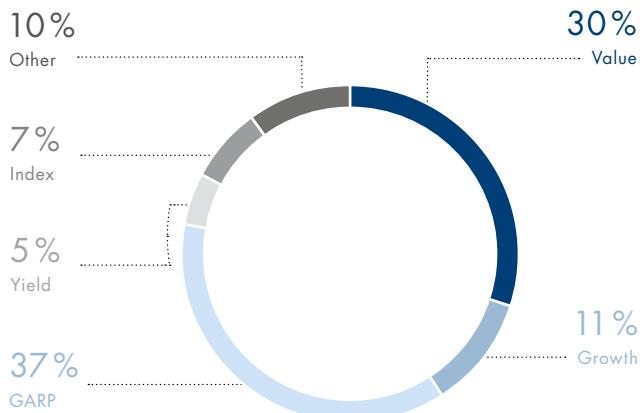
### Shareholder Structure by Geography as of Dec. 31, 2012



48.7% of total capital identified

Source: J.P.Morgan, Thomson One

### Shareholder Structure by Investor Type as of Dec. 31, 2012



51.2% of total capital identified | GARP – Growth at a reasonable price

Source: J.P.Morgan, Lionshares

**Key Share Data as of December 31, 2012**

	2012	2011
Total equity (in \$ thousands)	2,724,363	2,557,798
Issued shares		
Outstanding shares at December 31 (in thousands)	234,544	234,221
Weighted-average number of common shares outstanding – basic (in thousands)	235,582	233,850
Weighted-average number of common shares outstanding – diluted (in thousands)	240,746	239,064
Year-end market capitalization (in \$ million)	4,257	3,234
Year-end market capitalization (in € million)	3,225	2,494

**NASDAQ**

	2012	2011
Year-end price	\$ 18.15	\$ 13.81
High	\$ 19.41	\$ 22.20
Low	\$ 14.05	\$ 12.47
Average daily trading volume (in shares)	980,982	1,877,296

**Frankfurt Stock Exchange (XETRA)**

	2012	2011
Year-end price	€ 13.75	€ 10.65
High	€ 14.79	€ 15.12
Low	€ 10.70	€ 9.25
Average daily trading volume (in shares)	477,706	830,955

Our leaders recognize the importance of maintaining close relationships with investors and analysts. QIAGEN executives presented at approximately 35 brokerage conferences around the world in 2012. In addition to meetings during these conferences, QIAGEN executives participated in more than 200 visits to institutional investors in Europe, the United States, Canada, Asia and Australia during the year, and also were involved in numerous telephone calls. In total, these activities resulted in more than 1,000 direct discussions with investors and analysts.

QIAGEN held in-depth conference calls to discuss quarterly results during 2012. All QIAGEN-hosted investor presentations are accessible as webcasts on [www.qiagen.com](http://www.qiagen.com).

More than 30 analysts from international brokerages followed QIAGEN in 2012. At the end of 2012, approximately 32% of the analysts covering QIAGEN recommended buying QIAGEN common shares, while approximately 56% had a "hold" or "neutral" rating and 12% had a view of "sell" or "underperform."



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# MANAGEMENT REPORT

## Business and Operating Environment

### Overview

QIAGEN is the world's leading provider of innovative Sample & Assay Technologies, based on independent market studies of United States and European market shares for our products and technologies. Our automated systems and consumable products empower customers to transform raw biological samples into valuable molecular information. Sample technologies are used to isolate DNA (deoxyribonucleic acid), RNA (ribonucleic acid) and proteins from any biological sample, such as blood or tissue. Assay technologies are then used to amplify, enrich and provide results for analysis of biomolecules, such as the DNA of a virus or a mutation of a gene.

Our mission is to make improvements in life possible by enabling our customers to achieve outstanding success and breakthroughs in Molecular Diagnostics, Applied Testing, Pharma and Academia. QIAGEN began operations in 1986 by introducing to the emerging biotechnology sector a novel method that standardized and dramatically accelerated the extraction and purification of nucleic acids – biological molecules such as DNA and RNA that are essential for life as carriers of genetic information. Since the introduction of that first ready-to-use kit, QIAGEN has expanded to become the global leader with a broad offering of molecular technologies, including related automated systems.

Our products are used in virtually all areas of science focused on advancing knowledge about the molecular basis of life. QIAGEN has become a trusted partner by enabling customers to obtain exciting insights with products that are considered standards for quality and reliability. More than one billion biological samples are estimated to already have been prepared or analyzed using QIAGEN technologies in laboratories around the world. Net sales of \$ 1.25 billion in 2012 were composed of consumable kits and other revenues (86% of sales) and automated systems and instruments (14% of sales).

QIAGEN has leveraged its leadership position in Sample & Assay Technologies to build a strong global position in Molecular Diagnostics, now our largest customer class, accounting for 49% of net sales in 2012. The commercial applications of molecular technologies are transforming

healthcare by providing highly specific genetic information to guide prevention and treatment strategies.

With a focus on innovation, QIAGEN markets more than 500 core products that are distributed in thousands of variations and combinations. Innovative products are continually being introduced to address new market opportunities or extend the life of existing product lines. We have made a number of strategic acquisitions to enhance our technology and product offerings. We have funded our growth through internally generated funds as well as through debt offerings and private and public sales of equity securities. QIAGEN shares are listed on the NASDAQ exchange under the ticker symbol "QGEN" and on the Frankfurt Prime Standard as "QIA."

The company is registered under its commercial and legal name QIAGEN N.V. with the trade register (kamer van koophandel) of the Dutch region Limburg Noord under file number 12036979. QIAGEN N.V. is a public limited liability company (naamloze vennootschap) under Dutch law as a holding company. Our principal executive office is located at Spoorstraat 50, 5911 KJ Venlo, The Netherlands, and our telephone number is +31-77-320-8400.

As a holding company, QIAGEN conducts business through subsidiaries located throughout the world. Further information about QIAGEN can be found at [www.qiagen.com](http://www.qiagen.com). By referring to our website, we do not incorporate the website or any portion of the website by reference into this Annual Report.

### Operating Environment in 2012

#### Economic Environment

In 2012 an uneven global economy and uncertainties in the near-term outlook kept QIAGEN's business environment challenging and affected demand for our products in some geographic regions. The pace of economic growth slowed around the world, and the Euro area was in recession in 2012. Challenges in the broad economy included the sovereign debt crisis and austerity measures in Europe; fiscal negotiations and policy uncertainty in the United States; political turmoil and armed conflicts in the Middle East and North Africa; and deceleration in the still rapid growth of emerging markets such as China and India. For 2012, the Gross Domestic Product (GDP) in the 20 largest economies (known as "the G20") grew an estimated 2.8%, slower than the

3.8% growth in 2011 and the 5% expansion in 2010, the first year of recovery after the financial crisis and recession of 2008-09. For 2013, most analysts believe policies in the U.S. and Europe have averted an acute crisis but gradual economic improvement is the most likely scenario.

### **Industry Environment**

Industry developments affecting specific customer classes also have an influence on demand for QIAGEN products. In 2012, lingering economic weakness and unemployment in the U.S. and Europe damped utilization of healthcare services and diagnostic tests. In HPV testing in the U.S., QIAGEN faced pricing pressures amid increased competition. Customers in Academia faced limitations on public investments in life science research as fiscal austerity efforts by many governments threatened spending and grants for laboratories. In the Pharma industry, many companies continued to reduce spending and cut staff and projects amid consolidation and pricing pressures. On the other hand, the long-term growth trend in molecular technologies remains intact. Genomic information is transforming the practice of medicine, and healthcare providers are increasingly relying on molecular testing to diagnose diseases and guide treatments. Healthcare cost pressures support movement toward increasing lab efficiency through automation and use of standardized molecular diagnostics such as those provided by QIAGEN. Researchers in Academia and Pharma are using gene-based approaches to explore diseases and new ways to treat them, as well as to accelerate and manage clinical research. Technological breakthroughs such as the emergence of next-generation sequencing drive change in the industry, as well as demand for new products. Public and private users also continue to find new applications for DNA testing to solve crimes, improve productivity and safeguard food supplies.

### **Recent Developments**

QIAGEN achieved a number of recent strategic milestones in the development of our business:

- In May 2012, we acquired AmniSure International LLC, including the AmniSure® assay for determining whether a pregnant woman is suffering rupture of fetal membranes (ROM), a widespread cause of premature delivery and neonatal complications. This product, approved in the U.S. and many other markets, is expected to be catalytic for our Point of Need portfolio and beneficial to our presence in women's health. AmniSure provided a new growth driver for QIAGEN in 2012 as we integrated this Point of Need product into our commercial operations.

- In June 2012, we unveiled an initiative to enter the next-generation sequencing (NGS) market by creating an innovative sample-to-result NGS workflow designed to enable the routine use of this breakthrough technology in areas such as clinical research and molecular diagnostics. Adoption of NGS beyond life science research has been hampered by workflow challenges related in part to the larger number of samples processed in clinical settings. Our highly automated NGS offering will integrate a range of QIAGEN consumable and automation solutions, as well as components accessed through partnerships or acquired, including our acquisition of Intelligent Bio-Systems, Inc. in early 2012. Development of our unique GeneReader NGS benchtop sequencer, addressing many challenges for customers in clinical research and diagnostics, is on track. In late 2012 and early 2013, QIAGEN has launched 15 NGS products, all "universal" or compatible with any NGS platform, to enhance pre-analytical sample preparation, DNA library preparation and detection of targeted cancer genes. We plan to begin placing QIAGEN NGS workflows with selected customer groups during 2013.
- A landmark addition of test content was achieved in July 2012 when we received U.S. regulatory approval for our *therascreen*® KRAS RGQ PCR Kit, which provides guidance on the use of Erbitux® (cetuximab) as a treatment in patients with metastatic colorectal cancer. Leading U.S. laboratories covering approximately half of the current KRAS testing volumes in the U.S. adopted the *therascreen*® KRAS test by year-end. The first *therascreen*® companion diagnostic approved by the Food and Drug Administration (FDA) marked a milestone in global expansion of our Personalized Healthcare franchise, building on success in Europe and Japan, where we offer a range of companion diagnostics. In January 2012, for example, our *therascreen*® EGFR Mutation Detection Kit RGQ was approved in Japan to guide treatment of cancers targeted by certain anticancer drugs. In late 2012, the *therascreen*® EGFR RGQ PCR Kit was submitted to the FDA to guide treatment with afatinib, an investigational oncology compound developed by Boehringer Ingelheim that was granted FDA priority review status in January 2013.

- Our QIAxSymphony platform achieved several milestones as placements exceeded the target of 750 installed systems by year-end 2012. In July 2012, one of the modules in the QIAxSymphony family, the Rotor-Gene Q MDx real-time PCR cycler, received U.S. regulatory approval for use with our KRAS companion diagnostic kit, following clearance earlier

in the year to run our influenza A/B test kits. Also in July, the QIAsymphony RGQ platform received validation from an independent food safety group, the AOAC Research Institute, to run our *mericon® Salmonella spp.* kit in an automated workflow from food sample to final result. In 2012, China's State Food and Drug Administration (SFDA) approved QIAsymphony SP for automated sample preparation and QIAsymphony AS for assay setup workflows. With the 2010 SFDA clearance of the Rotor-Gene Q real-time PCR thermocycler, QIAGEN now offers customers in China the full QIAsymphony RGQ modular system.

- In September 2012, our emerging Point of Need franchise reached a milestone with the first regulatory approval in healthcare for the ESEQuant Lateral Flow System, a portable platform that QIAGEN acquired in 2010 and is developing for multiple applications. Under an agreement with Lepu Medical Technology (Beijing) Co., Ltd., a leading medical device company in China, the ESEQuant instrument will be deployed in emergency rooms to provide rapid results from Lepu's tests for cardiac markers – diagnosing acute myocardial infarction (heart attack) without sending samples out to a laboratory.
- In October 2012, we announced a collaboration with Bayer HealthCare for development and commercialization of companion diagnostics paired with novel Bayer drugs, initially to enhance the treatment of various solid tumors. The assays under development will be designed to run on our QIAsymphony family of automated instruments. In addition to the Bayer collaboration, we have a significant number of projects under way to co-develop and market companion diagnostics with leading pharmaceutical and biotech companies.
- In November 2012, we announced China's SFDA approved QIAGEN's *careHPV* Test and instrument platform, the first molecular diagnostic for human papillomavirus, or HPV, designed for low-resource clinical settings, such as areas lacking electricity, water or modern laboratories. Following product availability for *careHPV* in China in January 2013, we expect to introduce it in India and other emerging markets as approvals are received. In March 2012, we expanded access to our *digene* HPV Test across China through a co-marketing agreement with KingMed Diagnostics, China's largest independent laboratory network. The *digene* HPV Test was first registered in China in 2000 and is widely available in many of the country's top-tier hospitals and private labs. The KingMed agreement extends access to smaller hospitals, with KingMed functioning as a centralized laboratory.

- In January 2013, we announced three agreements to add biomarkers to our development pipeline for new companion diagnostics to guide treatment decisions in diseases such as rheumatoid arthritis, lung cancer and colorectal cancer. Most of the assays will be designed to run on the QIAsymphony RGQ automation system, as well as our NGS workflow currently in development.
- In February 2013, we announced a master collaboration agreement with Eli Lilly and Company for the development and commercialization of companion diagnostics for pairing with Lilly investigational and approved medicines across all therapeutic areas. The agreement creates a framework for expanding QIAGEN and Lilly's existing collaboration to development of additional potential products.

## Our Products

QIAGEN holds leadership positions in a wide range of customer classes for Sample & Assay Technologies. We offer more than 500 core consumable products (known as "kits") as well as a number of instrument solutions to fully automate the processing of almost all QIAGEN products used for sample preparation and subsequent analysis. The terms "Sample" and "Assay" Technologies define two phases of the process of unlocking valuable molecular information from raw biological materials, predominantly in digital form:

- **Sample Technologies:** QIAGEN has developed and advanced a broad range of technologies to extract and purify molecules of interest from biological samples such as blood, bone, tissue, etc. QIAGEN technologies ensure that a biological sample is consistently processed in a highly reproducible, standardized method with the highest level of quality before entering subsequent analysis with assay technologies.
- **Assay Technologies:** Building on its leadership in sample technologies, QIAGEN has developed assay technologies that enable the analysis of various kinds of molecules from virtually any biological sample. Assay technologies make information contained in isolated molecules visible and available for interpretation. Assays are tailor-made to address the specific demands of various research areas and commercial applications. Laboratory-developed tests (LDT) enable the customer to target molecules of interest for detection using reagents in the kit on platforms such as polymerase chain reaction (PCR). Commercially approved assays are preconfigured by QIAGEN to test for specific targets such as genetic mutations, gene expression levels,

influenza, human papillomavirus (HPV), tuberculosis (TB), hepatitis and herpes viruses, or human immunodeficiency virus (HIV).

These technologies provide two main categories of revenue streams for QIAGEN:

- **Revenues from consumables and related sales:** Consumable products, typically sample preparation or test kits and related sales, account for approximately 85-90% of our net sales. To maximize customer convenience and reduce user error, these kits contain all necessary reagents and buffers, and a manual including protocols and relevant background information. Each kit is sufficient to support a number of applications, varying from one to more than 1,000 tests.

Major applications for QIAGEN consumable products are plasmid DNA purification, RNA purification and stabilization; genomic and viral nucleic acid purification; nucleic acid transfection; PCR amplification; reverse transcription; DNA cleanup after PCR and sequencing; DNA cloning and protein purification. Our validated PCR assays enable detection of viral or bacterial pathogens and parasites in humans and animals, as well as pharmacogenomic testing and genotyping.

Our largest-selling product is the *digene* HC2 HPV Test, a signal-amplified test regarded as the “gold standard” in testing for high-risk strains of HPV, the primary cause of cervical cancer in women.

Related revenues include royalties, milestone payments from co-development agreements with pharmaceutical companies for companion diagnostics, payments from technology licenses and patent sales. We also have revenue from custom services, such as whole genome amplification services, DNA sequencing, and non-cGMP DNA production on a contract basis.

- **Automation platforms and instruments:** Our instrumentation systems automate the use of Sample & Assay Technologies into efficient solutions for a broad range of laboratory needs. These platforms, which account for approximately 10-15% of net sales, enable customers to perform reliable and reproducible nucleic acid sample preparation, assay setup, target detection and other laboratory tasks.

QIAGEN offers automated platforms for all phases of testing, from sample to result. Among them:

- QIAsymphony is an innovative, easy-to-use modular system that is making laboratory workflows more efficient and helping to disseminate standardized, regulator-approved diagnostics. The platform offers many features of interest to laboratories, such as continuous loading, random access, and the ability to process an almost unlimited range of sample types. QIAsymphony received the Association for Laboratory Automation’s New Product Award (NPA) following its introduction in 2008. In late 2010, we launched QIAsymphony RGQ, an integrated system that has started a new era of integrated workflow consolidation and laboratory automation, covering all steps from initial sample processing to final result. QIAsymphony RGQ gives customers access to a broad menu of commercially available assays while also allowing them to run their own PCR-based LDTs, which account for more than half of the volume of tests performed in many molecular diagnostic laboratories. In 2012, the installed base of QIAsymphony systems increased to more than 750 instruments worldwide, up from more than 550 at year-end 2011.
- Rotor-Gene Q, the world’s first rotary real-time PCR cycler system, uses real-time PCR reactions to make specific sequences of DNA and RNA visible through amplification and quantifiable through real-time measurement. This system enhances QIAGEN’s options to offer sample and assay technology solutions spanning from sample to result, and is an integral part of the QIAsymphony RGQ system.
- QIAensemble is a mid- to high-throughput automation platform for rapid turnaround of higher volumes of tests used for preventive screening, particularly for pathogens such as HPV. QIAGEN is developing automation upgrades to QIAensemble based on the current Rapid Capture System, as well as next-generation capabilities and expanded test menus. In late 2011 we launched QIAensemble Decapper, the first instrument to automate the handling of liquid-based cytology and other liquid samples in clinical laboratories – saving money and time by eliminating a series of tedious steps.
- PyroMark is a high-resolution detection platform based upon Pyrosequencing technology that allows for the real-time analysis and quantification of genetic mutations and DNA methylation patterns down to the single base pair level.

This enables users to identify even previously unknown mutations or variations in targeted DNA regions. This technology also can be employed in multiplex analysis for genetic and pathogen detection. Pyrosequencing plays a pivotal role in epigenetic research and also can be of great value to diagnostic laboratories running personalized healthcare and profiling assays.

- QIAcube, a sample processing instrument incorporating novel and proprietary technologies, allows users to fully automate the use of almost all of our products originally designed for manual processing of samples. The QIAcube received the NPA honor in 2007.
- QIAxcel, designed to take the place of traditional slab-gel analysis, can replace tedious and time-consuming methods of nucleic acid separation in low- to high-throughput laboratories. QIAxcel is characterized by unprecedented sensitivity and time to results for analysis of DNA fragments and RNA.
- ESEQuant Tube Scanners are portable, battery-operated optical measurement devices based on technology developed by ESE GmbH, a company we acquired in 2010. These UV and fluorescence detection systems enable point of need testing in healthcare and applied testing markets. The ESE technology permits low-throughput molecular testing in physician practices, emergency rooms, remote field areas, and other settings where a laboratory infrastructure is not accessible and fast turnaround is required.

### **Customers**

From the early days of the biotechnology revolution, we believed that Sample & Assay Technologies for nucleic acids would play an increasingly important role in cutting-edge biology and that major new commercial uses would develop for information extracted from DNA and RNA. Since 1986, we have been supplying customers with innovative proprietary products for the analysis of nucleic acids.

We sell our products, sample and assay kits known as consumables and automated instrumentation platforms using those technologies, to four major customer classes:

- **Molecular Diagnostics** – healthcare providers supporting many aspects of patient care including prevention, profiling of diseases, personalized healthcare and point of need testing.

- **Applied Testing** – government or industry customers using molecular technologies in fields such as forensics, veterinary diagnostics and food safety testing.
- **Pharma** – drug discovery, translational medicine and clinical development efforts of pharmaceutical and biotechnology companies.
- **Academia** – researchers exploring the secrets of life such as the mechanisms and pathways of diseases, and in some cases translating that research into drug targets or commercial applications.

### **Molecular Diagnostics**

The ability of advanced diagnostic technologies to unlock molecular information from patients is changing the practice of medicine, while creating a significant and growing market for nucleic acid sample preparation and assay technology products. In recent years, the advent of PCR and other amplification technologies has brought nucleic acid-based diagnostics into routine use in healthcare around the world.

This new generation of molecular diagnostics can be used to identify microorganisms, cancer cells, bacteria and viruses by searching for their specific nucleic acid sequences or to characterize previously unknown DNA sequences related to human diseases. Commercial applications for molecular diagnostics are multiplying as researchers identify new biological markers for disease and develop novel technologies for detection and analysis of those diagnostic clues from the human body.

The molecular diagnostics market, with sales estimated by industry experts at approximately \$5 billion in 2013 is still a small part of the global in vitro diagnostics market, but it is the fastest growing segment at a projected compound annual growth rate of 10% or more. Market penetration is still low in the U.S., other developed countries and emerging markets. However, given the advantages of precise genetic information over traditional tests, QIAGEN expects the molecular diagnostics market to provide significant growth opportunities over the long term.

Growth in the Molecular Diagnostics customer class is built upon four strategies for fighting disease, and QIAGEN is targeting each of these fields with a range of dedicated products and tailored marketing:

- **Prevention** – using advanced technologies to screen non-symptomatic patients as a preventive strategy, such as testing women for HPV to protect from cervical cancer or screening patients for latent TB infection to guard against active TB disease.
- **Profiling** – screening symptomatic patients to profile the precise type of disease, for example testing patients with flu-like symptoms to confirm or rule out dangerous strains such as the influenza type A (H1N1) swine flu.
- **Personalized Healthcare** – determining which patients are most likely to respond positively to particular therapies, such as landmark QIAGEN tests for testing the mutation status of genes such as KRAS, EGFR, BRAF and others that influence the effectiveness and safety profile of novel medicines for treatment of various cancers.
- **Point of Need** – enabling on-site diagnosis in physician practices, emergency rooms, remote field areas, and other settings where a laboratory infrastructure is not accessible and fast turnaround is required.

We offer one of the broadest portfolios of molecular technologies for human healthcare. Success in Molecular Diagnostics depends on the ability to analyze purified nucleic acid samples from a variety of sources, including blood, tissue, body fluids and stool, on automated systems that can handle hundreds of samples concurrently. Other key factors are the range of assays targeting various diseases and biomarkers, convenience and ease of laboratory workflow, versatility, reliability and standardization of the nucleic acid processing and detection procedures.

One of the largest Prevention markets is screening for HPV, a viral infection that is the primary cause of cervical cancer, which kills about 270,000 women a year worldwide. We are the global leader in HPV screening technologies, with our market-leading “gold standard” *digene* HC2 HPV Test and our emerging *careHPV* Test for use in low-resource regions of the world. In the United States, we sell our HPV products primarily for two FDA-approved indications: adjunctive primary screening with a Pap test for women age 30 and older, and follow-up testing of inconsistent Pap test results in women of any age. In Europe and the rest of the world, HPV testing is in varying stages of adoption. We are working closely with public health authorities and researchers on an increasing number of clinical trials and policy initiatives aimed at

expanding the use of HPV testing for prevention or follow-up to treatment of cervical cancer.

The early-warning QuantiFERON®-TB Gold test, which detects latent TB infection as a strategy for the prevention of TB disease in vulnerable populations, has become an important growth driver following QIAGEN’s 2011 acquisition of the product with its developer, the Australian firm Cellestis Ltd. Approximately one-third of the world’s population is infected with the tuberculosis bacterium but suffers no symptoms, a condition known as latent TB. However, about 5% to 10% of those patients at some point will develop active tuberculosis, a potentially life-threatening contagious disease that typically spreads from one active patient to 10 to 20 other people. The potential global market for latent TB detection is estimated at up to \$1 billion.

In Profiling, we offer an extensive range of Sample & Assay Technologies for use in the diagnosis of patients for various infectious diseases, including HIV, hepatitis and influenza. We are expanding this portfolio of assays and intend to gain regulatory approvals for these products in various geographic regions in the coming years. In 2012, our assay for detection of Influenza A/B, the *artus* Infl A/B RG RT-PCR Kit, was approved by the FDA, to run on the Rotor-Gene Q MDx platform. A key element of our global content expansion will be the use of these assay technologies on QIAsymphony RGQ.

In Personalized Healthcare, we offer companion diagnostics to guide the selection of medicines in treating cancer and other diseases based on a broad portfolio of more than 30 biomarkers. In July 2012, QIAGEN achieved a milestone in Personalized Healthcare with FDA approval of the *therascreen*® KRAS RGQ PCR Kit for use in patients with metastatic colorectal cancer. The U.S. rollout of *therascreen* KRAS builds on a strong global leadership position including Japan, where regulators approved the *therascreen* KRAS and EGFR kits in 2011, and Europe, where QIAGEN offers 10 CE-marked assays for personalized healthcare applications. QIAGEN has more than 15 projects under way to co-develop and market companion diagnostics with leading pharmaceutical and biotechnology companies. We have collaborative projects with high-profile companies such as Amgen, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb / ImClone, Eli Lilly, Pfizer and Sanofi. Ongoing acquisitions of biomarkers and other technologies contribute to our expanding co-development relationships. A key element of the global expansion in Personalized Healthcare is the ability of labs to efficiently use these assay technologies on QIAsymphony RGQ.

We market a range of automation systems designed for low-, medium-, and high-throughput nucleic acid sample preparation and handling tasks in laboratories performing molecular diagnostics.

The flagship platform is QIAsymphony, based on its unique characteristics. Nucleic acid samples purified on our instruments are ready for use in the demanding and sensitive downstream assays performed in molecular diagnostic applications. We offer closed and open assay technologies. Open assay technologies contain PCR reagents to identify molecules of choice. Closed assays, diagnostics with predefined targets, include multiplexing and other pathogen or genetic mutation detection assays such as tests for HIV, tuberculosis, influenza or hepatitis. We market assays directly to end customers via our sales channels, and selected assays through major diagnostic partners with complementary customer groups. In addition, we intend to enter into partnerships or other agreements with companies to broaden the distribution of our products.

### **Applied Testing**

Use of molecular technologies is growing in more and more areas of life as industry and government organizations apply standardized sample preparation and assay solutions to diverse needs. Applied Testing is our term for applications outside of human healthcare and research – such as human identification and forensics, food and water safety, and veterinary testing. The value of genetic “fingerprinting” has been shown for criminal investigations or clarification of paternity or ancestry, public policy compliance for food safety and genetically modified organisms (GMOs), and containment of diseases in commercial livestock. Molecular testing can be performed by well-trained researchers in fully equipped laboratories, and increasingly also by less-trained personnel provided with easy-to-use, reproducible and standardized methods for point of need testing. Our manual DNA and RNA purification methods and the automated solutions on QIAsymphony, QIAcube, EZ1 Advanced, BioRobot EZ1 and other products, as well as our amplification enzymes and quantitative assays, address the needs in these markets.

### **Pharma**

QIAGEN is a significant supplier for pharmaceutical and biotechnology companies. Drug discovery and translational research efforts increasingly employ genomic information, both to guide research in diseases and to differentiate the patient populations most likely to respond to particular therapies in clinical settings. We estimate that about half of QIAGEN sales in this customer class support research, while

the remaining half of sales support clinical development processes, including the stratification of patient populations based on genetic information. QIAGEN’s GeneGlobe online portal ([www.geneglobe.com](http://www.geneglobe.com)) offers scientists an industry-leading source of information with searchable data on 60,000 genomic technologies for disease pathways, including annotations and references, to guide research and to enable ordering from this broad portfolio of assays.

As new drugs are commercialized, testing technologies developed in parallel with those therapies can move from Pharma R&D into the healthcare market as companion diagnostics, which are marketed in our Molecular Diagnostics customer class. Healthcare professionals use companion diagnostics to customize treatment by testing for specific genetic biomarkers that help determine the safety and efficacy profiles of drugs in individual patients, achieving the best possible therapeutic results and avoiding unnecessary treatments. In the coming years, we expect a wave of newly discovered biomarkers and companion diagnostics to transform the treatment of an increasing number of diseases.

In addition to the broad portfolio of molecular technologies, QIAGEN brings to the Pharma market a full infrastructure for co-development programs, intellectual property on platforms and content, extensive regulatory experience, global reach in our sales channels, and independence as a company focusing exclusively on these types of technologies.

### **Academia**

QIAGEN provides Sample & Assay Technologies to leading research institutions around the world. Many academic laboratories continue to utilize manual, labor intensive methods for nucleic acid separation and purification. Recognizing the opportunity to replace traditional methods with reliable, fast, highly reproducible, and high-quality nucleic acid extraction and purification technologies, QIAGEN has concentrated product development and marketing efforts on the research markets in industry and Academia.

As academic institutions increasingly embrace translational research, bridging from discoveries to practical applications in medicine, the academic market also supports our presence in the Molecular Diagnostics and Pharma customer classes. Research in university settings often helps in the development of specific technologies for targeted biomolecules, and academic research also can result in scientific publications that validate the usefulness of QIAGEN technologies for specific applications.

## Geographic Markets

QIAGEN currently markets products in more than 100 countries. The following table shows total revenue by geographic market for the past three years (net sales are attributed to countries based on the location of the subsidiary making the sale, as certain subsidiaries have international distribution):

\$ 1,000	2012	2011	2010
<b>Net sales</b>			
Americas:			
United States	518,130	466,502	472,682
Other Americas	42,921	55,137	50,912
Total Americas	561,051	521,639	523,594
Europe	459,321	444,441	398,029
Asia Pacific & Rest of World	234,084	203,667	165,808
<b>Total</b>	<b>1,254,456</b>	<b>1,169,747</b>	<b>1,087,431</b>

Expansion into high-potential geographic markets is a core priority. Our top seven emerging markets (Brazil, Russia, India, China, South Korea, Mexico and Turkey) represented more than 10% of net sales in 2012. We have built a presence in China with approximately 400 employees, which represents our third-largest geographic market in terms of sales. In 2012, we added subsidiaries in Russia and Poland. In 2011, new subsidiaries were created in India and Taiwan, further expanding our presence in Asia.

## Strategic Initiatives

We believe the relevant global market for molecular diagnostics and life science research products totals approximately \$70 billion. Among the fundamental growth drivers in the business environment are ongoing breakthroughs and insights into molecular biology, new technologies to analyze molecular information, improvements in the quality of healthcare and reductions in cost using diagnostics, increasing demands for quality, and revenue streams made possible through consumable products.

We have grown substantially in recent years with a flexible strategy that includes developing innovative new products, partnering, and acquiring companies or technologies to complement our portfolio.

QIAGEN is pursuing four strategic initiatives that aim to:

- Drive platform success. We develop innovative instruments that enable our customers to efficiently perform molecular testing in a wide range of applications. Expanding the installed base of our instruments, particularly the QIAsymphony automation platform, also leads to growing sales of our consumable test kits.
- Add content. We continually bring new tests to market across all customer classes, meeting urgent market needs in the diagnosis of disease, life science research and other applications. In molecular diagnostics we focus on standardized tests approved by regulatory agencies for routine use in healthcare. Expanding the menu of tests available for efficient workflow on our instruments also enhances the value of our platforms to laboratories.
- Broaden geographic presence. We systematically establish and expand our presence in attractive markets around the world, especially high-growth emerging markets. We help developing countries bring state-of-the-art capabilities into their healthcare and research infrastructures. We also develop molecular technologies to meet specific needs in medicine or other applications for emerging markets such as China.
- Grow efficiently and effectively. We pursue sustained growth and improved profitability through operational improvements and a culture that encourages focus, accountability and entrepreneurial decision-making. Our R&D, regional marketing and sales teams are integrated into the Molecular Diagnostics and Life Sciences business areas to connect our innovation and commercial activities directly with growing markets.

## Research and Development

We are committed to expanding our global leadership in Sample & Assay Technologies. Our strategy for managing innovation focuses on addressing the most significant unmet medical and scientific needs. We target our resources to develop the most promising technologies for use by our customers in Molecular Diagnostics, Applied Testing, Pharma and Academia – and to meet the needs of healthcare professionals and scientists in key geographic markets.

Innovation at QIAGEN follows parallel paths:

- Creating new systems for automation of workflows – platforms for laboratories, hospitals and other users of these novel molecular technologies.
- Expanding our broad portfolio of “content” – in particular, novel assays to detect and characterize molecular structures and biomarkers for disease or genetic identification.

Our research and development investments are among the highest compared to other companies in our industry. Approximately 700 employees in research and development work in eight centers of excellence on four continents. Our comprehensive intellectual property portfolio spans more than 1,000 granted patents and more than 900 pending applications.

Innovations in instrumentation are strengthening our leadership in the automation of laboratories, driving dissemination of molecular technologies in healthcare and other fields, and generating increased demand for our consumable products. We continue to extend our modular, medium-throughput QIAxSymphony platform, enabling hospitals and other customers to adopt or greatly expand their use of molecular diagnostics. QIAxSymphony RGQ, designed to allow fully integrated processing from initial sample to final result, has expanded the QIAxSymphony installed base since the launch of the fully integrated system in late 2010. We plan to integrate modules in the future for specialized needs such as next-generation sequencing. In late 2011, we launched the QIAensemble Decapper, the first instrument that automates the tedious process of handling liquid clinical sample vials, enhancing our high-throughput QIAensemble platform. In 2012, we announced an initiative to develop a new platform for NGS with the workflow characteristics needed to expand NGS from its current focus in life science research into widespread use in healthcare and clinical research.

We are commercializing a deep pipeline of content: molecular assays for preventive screening and diagnostic profiling of diseases, tests for important biomarkers to guide personalized cancer therapies, and assays for a broad range of other targets. The rollout of QIAxSymphony RGQ is accompanied by an extensive development program involving assays for Molecular Diagnostics and other customer classes. U.S. regulatory submissions made in 2012 include a companion diagnostic for a new cancer drug targeting EGFR (epidermal growth factor receptor) and our pre-molecular assay for cyto-

megalovirus infection (CMV) in transplant patients. In Applied Testing, QIAGEN continues to develop new content for human identification, food safety and veterinary diagnostics. We are also expanding our extensive portfolio of products for disease pathway research by Pharma and Academic customers. In addition, we are developing assays for specific applications in key markets such as China and Japan. The total combined addressable markets for our current assay development portfolio approach \$ 1 billion in potential annual sales.

In addition, we are investing in the co-development of companion diagnostics for personalized healthcare through projects with pharmaceutical and biotech companies. These programs typically begin with development of targeted assays to assist our customers in the clinical development of new drugs by identifying patient populations most likely to respond favorably to specific therapies. The collaborations have potential to develop into companion diagnostics marketed commercially along with the new drugs.

### **Sales and Marketing**

We market our products in more than 100 countries throughout the world. We have established subsidiaries in markets we believe have the greatest sales potential in the Americas, Europe, Australia and Asia. We have established a network of experienced personnel who sell our products and provide direct support to customers. A significant number of marketing and sales staff members are experienced scientists with academic degrees in molecular biology or related areas. In addition, business managers oversee relationships with key accounts to ensure that we are serving their needs on the commercial side, such as procurement systems, financing arrangements, data on the costs and value of our systems, and collaborations among organizations. We also have specialized independent distributors and importers in many markets.

Our marketing strategy focuses on providing high-quality products that offer customers unique value, coupled with commitment to technical excellence and customer service. We have developed a range of marketing tools to provide customers with direct access to technical support and to inform them of new product offerings, as well as to enhance our reputation for technical excellence, high-quality products and commitment to customer service. One such tool is our technical service hotline, which allows existing or potential customers to discuss a wide range of technical questions regarding our products and related molecular biology procedures, via phone or e-mail, with Ph.D. and M.Sc. scientists in our technical service group. Frequent communication with customers

enables us to identify market needs, gain early insight into new developments and business opportunities, and address them with new products.

Our GeneGlobe online portal ([www.geneglobe.com](http://www.geneglobe.com)) has become a valuable outreach to life science researchers in Pharma and Academia by providing an industry-leading resource on disease pathways, biomarkers and genomic information. GeneGlobe provides searchable, annotated data on 60,000 pathway and gene-related technologies, with links to order products related to each avenue of investigation.

We also distribute several publications, including our catalog, to existing and potential customers worldwide, providing new product information, product updates, and articles by customers and by our scientists about existing and new applications. Our website ([www.qiagen.com](http://www.qiagen.com)) contains a full online product catalog and ordering system, as well as a host of support tools, scientific design tools and other resources. We have full Japanese and Chinese language versions of our website, and some information is available on our site in French, German and Korean to support these markets. Information contained on our website, or accessed through it, is not part of this Annual Report. In addition, we hold numerous scientific seminars to present technical information at leading clinical, academic and industrial research institutes worldwide. We conduct direct marketing campaigns to announce new products or offer special promotions, and we offer personalized electronic newsletters with useful information for molecular biology applications.

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

### **Seasonality**

Our business does not experience significant, predictable seasonality. Historically, a significant portion of our sales have been to researchers, universities, government laboratories and private foundations whose funding is dependent upon grants from government agencies, such as the National Institutes of Health and similar bodies. To the extent that our

customers experience increases, decreases or delays in funding arrangements and budget approvals, and to the extent that any of our customers' activities are slowed, such as during times of higher unemployment, vacation periods or delays in the approval of government budgets, including the U.S. federal government's budget, we may experience fluctuations in sales volumes during the year or delays from one period to the next in the recognition of sales.

### **Intellectual Property, Proprietary Rights and Licenses**

We have made and expect to continue to make investments in intellectual property. In 2012, our purchases of intangible assets totaled \$26.1 million. While we do not depend solely on any individual patent or technology, we are significantly dependent in the aggregate on technology that we own or license. Therefore, we consider protection of proprietary technologies and products one of the major keys to our business success. We rely on a combination of patents, licenses and trademarks to establish and protect proprietary rights. As of December 31, 2012, we owned 193 issued patents in the United States, 143 issued patents in Germany and 767 issued patents in other major industrialized countries. We have over 972 pending patent applications. Our policy is to file patent applications in Western Europe, the United States and Japan. U.S. patents have a term of 17 years from the date of issue (for patents issued from applications submitted prior to June 8, 1995), or 20 years from the date of filing (in the case of patents issued from applications submitted on or after June 8, 1995). Patents in most other countries have a term of 20 years from the date of filing the patent application. We intend to aggressively prosecute and enforce patents and to otherwise protect our proprietary technologies. We also rely on trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

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

## Competition

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

We also experience competition in various markets from other companies providing sample preparation products in kit form and assay solutions. These competitors include, but are not limited to, Promega Corp., EMD Millipore or Merck Millipore, and Macherey-Nagel GmbH for nucleic acid separation and purification; Life Technologies Corp. and Promega Corp. for assay solutions and for transfection reagents; and Sigma-Aldrich Corp. and Fisher Scientific for protein fractionation products. We believe our proprietary technologies and products offer significant advantages over competitors' products with regard to purity, speed, reliability and ease of use.

The medical diagnostics and biotechnology industries are subject to intense competition. In our HPV franchise within our molecular diagnostics customer class, we face competition from well-established diagnostic technologies, such as cytology, and from emerging HPV testing approaches, such as signal amplified testing, research-based PCR, other indicators of disease and other traditional testing methods developed by laboratories. Our competitors include companies such as Roche Diagnostics GmbH and Hologic, Inc., which have been marketing FDA-approved HPV testing products in the U.S. in recent years. We expect competition to intensify, but our leading position in the HPV market is supported by our marketing efforts and the data supporting our *digene* HPV Test. We believe we have a competitive advantage driven by the fact that close to 90 million of these tests have been distributed worldwide as well as a multitude of clinical trials encompassing more than one million women. These clinical trial results, many of which have been published in peer-reviewed journals such as the New England Journal of Medicine, have validated that our HPV test products, used alone or in conjunction with the Pap test, demonstrate high clinical sensitivity and high negative predictive value for

diagnosis of cervical disease and cancer. In addition to the industry-leading clinical performance of our assay, our automation systems offer other competitive benefits, for the high-volume HPV testing market, including performance and reliability, ease of use, standardization, cost, proprietary position and regulatory approvals. The QIAensemble Decapper, a unique instrument that automates time-consuming manual steps for handling liquid sample vials, was added for the U.S. market in late 2011. A number of major U.S. customers for HPV screening products operate under multiyear contracts with us, in which we provide competitive pricing and other benefits.

Some of our other products within our molecular diagnostics customer class, such as tests for Chlamydia, Gonorrhea, hepatitis B virus, herpes simplex virus and CMV, compete against existing screening, monitoring and diagnostic technologies, including tissue culture and antigen-based diagnostic methodologies. Our competitors for gene-based diagnostic probes include Roche Diagnostics, Abbott, Siemens and Hologic. We believe the primary competitive factors in the market for gene-based probe diagnostics and other screening devices are clinical validation, performance and reliability, ease of use, standardization, cost, proprietary position, competitors' market shares, access to distribution channels, regulatory approvals and availability of reimbursement.

We do not believe our competitors have the same comprehensive approach to Sample & Assay Technologies as we do or the ability to provide the broad range of technologies and depth of products and services that we offer. With our complete range of manual and fully automated solutions, we believe we offer the value of standardization of procedures and, therefore, more reliable results. We also believe our integrated strategic approach gives us a competitive advantage. The quality of sample preparation – an area in which we have a unique market and leadership position – is a key prerequisite for reliable molecular assay solutions, which increasingly are being applied in emerging markets such as Molecular Diagnostics and Applied Testing.

Current and potential competitors may be in the process of seeking FDA or foreign regulatory approvals for their respective products. Our continued future success will depend in large part on our ability to maintain our technological advantage over competing products, expand our market presence and preserve customer loyalty. There can be no assurance that we will be able to compete effectively in the future or that development by others will not render our technologies or products non-competitive.

## **Suppliers**

As part of our quality assessment procedures, we periodically evaluate the performance of our raw material and component suppliers, potential new alternative sources of such materials and components, and the risks and benefits of reliance on our existing suppliers. We buy materials for our products from many suppliers, and are not dependent on any one supplier or group of suppliers for our business as a whole. Raw materials generally include chemicals, raw separation media, biologics, plastics and packaging. Raw materials are generally readily available at competitive, stable prices from a number of suppliers. Certain raw materials are produced under our specifications, so we closely monitor stock levels to maintain adequate supplies. We believe we maintain inventories at a sufficient level to ensure reasonable customer service levels and to guard against normal volatility in availability.

## **Government Regulations**

We are not subject to direct regulation other than regulation generally applicable to businesses pursuant to various laws and regulations in effect in the different jurisdictions in which we operate, including laws and regulations applicable to environmental matters, such as the handling and disposal of hazardous wastes.

Our research and development activities involve the controlled use of small amounts of hazardous materials, chemicals and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by applicable regulations, such as the United States Occupational Safety and Health Administration's, or OSHA, Hazard Communication and Occupational Exposure to Hazardous Chemicals in Laboratories standards, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could have a material adverse effect on us.

We also comply with the OSHA Bloodborne Pathogens standard and the Center for Disease Control / National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories standards for the handling of biological materials and comply with the United States Department of Transportation and International Air Transport Association regulations for the shipping of our kits which contain materials classified as hazardous. There are other federal, state and local laws and regulations applicable to our business, including those of the United States Environmental Protection

Agency and the Maryland Department of the Environment. However, we do not expect that compliance with governmental regulations to which we are subject will have a material effect on our capital expenditures, earnings or competitive positions.

International sales of in vitro diagnostic (IVD) and other medical devices are subject to the regulatory requirements of each country or defined economic region, such as the European Union. The regulatory review process varies from country to country and many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on devices.

In the United States, IVDs are regulated by the FDA as medical devices. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, premarket notification and adherence to FDA's quality system regulations, which are device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and postmarket surveillance. Class III devices are subject to most of the previously identified requirements as well as to premarket approval. Class I devices are exempt from premarket submissions to the FDA; most Class II devices require the submission of a 510(k) premarket notification to the FDA; and Class III devices require submission of a premarket approval application, or PMA. Most in vitro diagnostic kits are regulated as Class I or Class II devices and are either exempt from premarket notification or require a 510(k) submission.

A 510(k) notification must demonstrate that a medical device is substantially equivalent to another legally marketed device, termed a "predicate device," that is legally marketed in the United States and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate, or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. Most 510(k)s do not require clinical data for clearance, but a minority will. The FDA is supposed to issue a decision letter within 90 days of receipt of the 510(k) if it has no additional questions or send a first action letter requesting additional information

within 75 days. Requests for additional data, including clinical data, will increase the time necessary to review the notice. If the FDA does not agree that the new device is substantially equivalent to the predicate device, the new medical device is automatically classified as a Class III device for which a PMA will be required. However, the sponsor may petition the FDA to make a risk-based determination that the device does not pose the type of risk associated with Class III devices and down-classify the device to Class I or Class II.

Class III devices, such as our HC2 HPV test, require the submission and approval of a PMA prior to product sale. The PMA process is more complex, costly and time-consuming than the 510(k) process. A PMA must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial. After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA of 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. The total process may take several years, and the FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Product changes after approval typically require a supplemental submission with FDA review cycles ranging from 30 to 180 days.

Any products manufactured or distributed pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the use of the device, and restrictions on advertising and promotion. Device manufacturers are required to register their establishments and list their devices with the FDA and are subject to periodic inspections by the FDA and certain state agencies. Noncompliance with applicable FDA requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the FDA to grant 510(k) or PMA approval for devices, withdrawal of 510(k) clearances and/or PMA approvals, or criminal prosecution.

Some of our test kits are sold for research use only in the United States. We do not promote these tests for clinical diagnostic use, and they are labeled "For Research Use Only" or RUO, as permitted by FDA regulations.

Receipt and maintenance of regulatory authorization to market and sell our products is vital to future success. In addition to seeking regulatory authorizations for our products, we work with other companies to seek regulatory clearance or approval for use of their products to provide the specimens necessary to perform our diagnostic tests. The time, money and resources required for new product clearances or approvals by the FDA and foreign authorities is unpredictable, and the necessary approvals or clearances may not be granted on a timely basis or at all. Delays or failure to receive such approvals or clearances could have a material adverse effect on our business, financial condition and results of operations.

The Physician Payment Sunshine Act, or Sunshine Act, which was enacted as part of the Affordable Care Act, or ACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. The Final Rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013, to December 31, 2013, is due March 31, 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from \$1,000 to \$10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (up to a maximum per annual report of \$1 million). We will be required to collect data on these payments and report such payments.

Recent U.S. legislation has been enacted to improve transparency and accountability concerning the sourcing of "conflict minerals" from mines located in the conflict zones of the Democratic Republic of Congo (DRC) and its adjoining countries. The term conflict minerals currently encompasses tantalum, tin, tungsten (or their ores) and gold. Certain of our instrumentation product components which we purchase from

third party suppliers do contain gold. This U.S. legislation requires manufacturers, such as us, to investigate our supply chain and disclose if there is any use of conflict minerals originating in the DRC or adjoining countries. We are currently evaluating the potential impact of, and developing an implementation strategy for, this legislation.

### **Organizational Structure**

QIAGEN N.V. is the holding company for more than 50 consolidated subsidiaries, many of which have the primary function of distributing our products and services on a regional basis. Certain subsidiaries also have research and development or production activities.

### **Property**

Our production and manufacturing facilities for consumable products are located in Germany, the United States, China, France, and the United Kingdom. Our instrument production facilities are located in Switzerland. In recent years, we have made investments in automated and interchangeable production equipment to increase our production capacity and improve efficiency. Our production and manufacturing operations are highly integrated and benefit from sophisticated inventory control. Production management personnel are highly qualified, and many have advanced degrees in engineering, business and science. We also have installed and continue to expand production-planning systems that are included in our integrated information and control system based on the SAP R/3 business software package from SAP AG. Worldwide, we use SAP software to integrate most of our operating subsidiaries. Capital expenditures for property, plant and equipment totaled \$ 102.0 million, \$ 86.8 million, and \$ 79.7 million for 2012, 2011 and 2010, respectively.

We have an established quality system, including standard manufacturing and documentation procedures, intended to ensure that products are produced and tested in accordance with the FDA's Quality System Regulations, which impose current Good Manufacturing Practice (cGMP) requirements. For cGMP production, special areas were built in our facilities in Hilden, Germany, and Germantown and Gaithersburg, Maryland. These facilities operate in accordance with cGMP requirements.

The consumable products manufactured at QIAGEN GmbH in Germany, and QIAGEN Sciences, Inc. and QIAGEN Gaithersburg, Inc., both in Maryland, are produced under ISO 9001: 2000, ISO 13485:2003 for Medical Devices, and ISO 13485:2003 CMDCAS, and the EC Directive 98 /79 /EC

for medical devices. QIAGEN Instruments AG in Switzerland, which produces the majority of our instrumentation product line, is also ISO 9001: 2000 and 13485:2003 certified. Our certifications form part of our ongoing commitment to provide our customers high-quality, state-of-the-art Sample & Assay Technologies and to the development of our Total Quality Management system.

Our facilities in Hilden, Germany, currently occupy a total of approximately 755,000 square feet, some of which is leased pursuant to separate contracts, the last of which expires in 2018. Our production capacity is increased through our manufacturing and research facilities in the United States. QIAGEN Sciences, LLC owns a 27-acre site in Germantown, Maryland. The 285,000 square foot Germantown facility consists of several buildings in a campus-like arrangement and is intended to accommodate over 500 employees. There is room for future expansion of up to 300,000 square feet of facility space. We lease a facility in Gaithersburg, Maryland, comprising a total of 150,000 square feet and 40,000 square feet in Frederick, Maryland, for manufacturing, warehousing, distribution and research operations.

In 2009, we purchased additional land adjacent to our facility in Hilden, Germany, for EUR 2.5 million (approximately \$ 3.2 million) and began construction to further expand our facilities for research and development and production. In 2010, we began construction on expansion of our research, production and administrative space in Germantown, Maryland. While the construction in Germany is complete, the U.S. expansion projects are expected to continue into 2013, with both projects estimated at a total cost of approximately \$ 94.0 million, of which \$ 86.4 million had been incurred as of December 31, 2012. We anticipate being able to fund these expansions with cash generated by operating activities.

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

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

## Opportunities and Risks

QIAGEN, like any other company, has business operations that involve significant opportunities and risks. Effective management is paramount to safeguarding the sustainable value creation, and the central task of the leadership team. Managing opportunities and risks is an integral part of the corporate governance system in place throughout QIAGEN, not the task of one particular organizational unit. According to our current assessment, we consider the opportunities and risks to be manageable and the survival of QIAGEN not to be endangered at the time of this report; QIAGEN is well prepared to meet future challenges.

### Opportunities

As an international company, QIAGEN is exposed to a wide variety of developments in the various markets in which it operates. Our mission is to "make improvements in life possible" by capturing growth opportunities presented by the dissemination of molecular technologies across the four customer classes in Molecular Diagnostics, Applied Testing, Pharma and Academia. Due to increased life expectancy for people living in developed countries, and also the dynamic growth of healthcare demand in many emerging markets, the need for innovative diagnostics is increasing at a marked pace. This is underscored by the proven benefits of diagnostics to improve healthcare outcomes, particularly the advent of companion diagnostics to personalize healthcare, while still representing a small fraction of overall healthcare expenditures. Our internal R&D activities present major opportunities, and we are working to find new products and improve existing ones across our portfolio of Sample & Assay Technologies. We also continuously evaluate potential additional opportunities across our four customer classes as an integral part of our strategy. All of these factors represent future growth opportunities for QIAGEN.

### Risk Management

Our risk management approach embodies the key elements of a sound management system including (1) active board and senior management involvement; (2) adequate policies and procedures; (3) adequate risk management, monitoring and information systems; and (4) comprehensive internal controls.

The Company is managed by a Managing Board and an independent Supervisory Board appointed by the General Meeting of Shareholders. One of the Managing Board's responsibilities is the oversight of the Company's risk man-

agement system. The Managing Board has developed and implemented strategies, controls and mitigation measures to identify current and developing risks as part of our risk management system. Risk management policies and procedures are embodied in our corporate governance, code of ethics and financial reporting controls and procedures. A variety of functional experts evaluate these business risks, attempting to mitigate and manage these risks on an ongoing basis.

Identified risks are subdivided into three types:

- A base business risk is specific to us or our industry that threatens our current and existing business;
- A business growth risk is a risk specific to us or our industry that threatens our future business growth; and
- An underlying business risk comprises risks that are not specific to us or our industry but apply to a larger number of public companies.

All identified risks are evaluated based on their likelihood of occurring and their potential impact (estimated in monetary terms) in disrupting our progress in achieving our business objectives. The overall risk management goal is to identify risks that could significantly threaten our success and to allow management on a timely basis the opportunity to successfully mitigate such risks. The results of the risk assessment and any updates are reported to the Audit Committee on a regular basis. Each quarter a detailed risk reporting update is provided to the Audit Committee for specific risks which have been newly identified or have changed since the last assessment. On a semi-annual basis the overall risk inventory is updated for all risks that are categorized as either a base business risk or a risk to business growth. A detailed review of all underlying business risks is done every year. At least once a year, the Supervisory Board discusses the corporate strategy and business risks as well as the results of an assessment by the Managing Board and the Audit Committee on the structure and operations of the internal risk management and control systems, including any significant changes.

Our corporate governance structure is based on a strong framework of the responsibilities of our Managing and Supervisory Boards and the function of the Audit Committee of the Supervisory Board. We maintain an adequate internal control over financial reporting to ensure the integrity of financial reporting. Additionally, we maintain a Compliance Committee under the leadership of the Chief Financial

Officer, who is also a member of the Managing Board. The Compliance Committee consists of senior executives from various functional areas who are responsible to ensure compliance with legal and regulatory requirements in addition to overseeing the communication of corporate policies.

#### Risk Types

	Identification and monitoring of competitive threats to the business
	Monitoring complexity of product portfolio
	Monitoring dependence on key customers for single product groups
	Dependence on individual production sites or suppliers
	Evaluating purchasing initiatives, price controls and changes to reimbursements
	Monitoring of production risks, including contamination prevention, high-quality product assurance
	Ensuring ability to defend against intellectual property infringements and maintain competitive advantage after expiration
Business Growth Risk	Managing development and success of key R&D projects
	Managing successful integration of acquisitions to achieve anticipated benefits
Underlying Business Risk	Financial Risks including Economic risk and fluctuations in currency exchange rates
	Financial Reporting Risk including monitoring multi-jurisdiction tax compliance
	Evaluating possible asset impairment events
	Compliance and Legal risks including safety in operations and environmental hazard risks, compliance with various regulatory bodies and pending regulatory product approvals
	Risks of FCPA or anti-trust concerns arising from a network of subsidiaries and distributors in foreign countries

#### Risks

This section outlines a number of significant risks to which QIAGEN is exposed. The order in which the risks are listed is not intended to imply any assessment as to the likelihood of their materialization or the extent of any resulting damages. They should also be seen in light of the opportunities that could result from positive trends. For further information, refer to the risks and uncertainties discussed under the caption "Risk Factors" in Item 3 of the 2012 Annual Report on Form 20-F on file with the U.S. Securities and Exchange Commission and throughout this Annual Report.

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

Our business has grown rapidly, with total net sales increasing to \$ 1.25 billion in 2012 from \$ 1.01 billion in 2009. We have made several acquisitions in recent years, including AmniSure in 2012 and Cellectis Ltd. and Ipsogen S.A. in 2011. Other acquisitions include SABiosciences and DxS Ltd. in 2009; Corbett Life Science Pty. Ltd., or Corbett, in 2008; and Digene Corporation, or Digene, in 2007. We intend to identify and acquire other businesses in the future that support our strategy to build on our global leadership position in Sample & Assay Technologies. The successful integration of acquired businesses requires a significant effort and expense across all operational areas.

We have also made significant investments to expand our business operations. In January 2009, we purchased land adjacent to our facility in Germany and in August 2009 began a major expansion project to create additional facilities for research and development as well as to expand production capacity. This expansion project was completed in early 2012. In addition, we began a project in June 2010 to expand our facility in Germantown, Maryland, for research, production and administrative space, and this project is expected to continue into 2014. The rapid expansion of our business and the 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, integrate acquired businesses, and effectively address new issues related to our growth as they arise. There can be no assurance that we will be able to manage our recent or any future expansion or acquisitions successfully, and any inability to do so could have a material adverse effect on our results of operations.

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

During the past several years, we have acquired and integrated a number of companies through which we have gained access to new technologies, products and businesses

that complement our internally developed product lines. In the future, we expect to acquire additional technologies, products or businesses to expand our operations. Our failure to successfully address risks in the future may prevent us from achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all.

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

Rapid technological change and frequent new product introductions are typical in the markets we serve. Our 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, or such products suffer significant delays in development or are not accepted in the market, we may lose market share to our competitors, which will be difficult or impossible to regain. An inability to successfully develop and introduce new products, for technological or other reasons, could reduce our growth rate or otherwise have an adverse effect on our business.

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.

Important new product programs underway include our modular QIASymphony automation platform, our next generation sequencing platform and our high-throughput QIAensemble automation platform and related Sample & Assay Technologies.

*Global economic conditions could adversely affect our business, results of operations and financial condition.*

Our results of operations could be materially affected by adverse general conditions in the global economy and global financial markets. In times of economic hardship or high unemployment, patients may decide to forego or delay routine tests, in particular our HPV test used to screen women for risk of cervical cancer. Changes in the availability or reimbursement of our molecular diagnostic testing products by

insurance providers and healthcare maintenance organizations could also have a significant adverse impact on our results of operations.

Access to financing in the global financial markets has also been adversely affected for many businesses during the recent challenging economic times and public debt crisis. The uncertainty surrounding the resolution of the economic and sovereign debt crisis in Europe continues to have a negative impact on financial markets and economic conditions more generally. Our customers may face internal financing pressures that adversely impact spending decisions, the ability to purchase our products or that lead to a delay in the collection of receivables and thus negatively impact our cash flow. A severe or prolonged economic downturn could result in a variety of risks to our business that would adversely impact our results of operations, including the reduction or delay in planned improvements to healthcare systems in various countries, the reduction of funding for life sciences research, and intensified efforts by governments and healthcare payors regarding cost-containment efforts.

Our results of operations could also be negatively impacted by automatic U.S. government spending cuts ("sequestration") that may take effect in 2013. These conditions may add uncertainty to the timing and budget for investment decisions by our customers, particularly, researchers, universities, government laboratories and private foundations whose funding is dependent upon grants from government agencies, such as the National Institutes of Health and similar bodies.

*Our concentration of a significant portion of revenues in products related to HPV testing increases our dependence on that product group's success, our reliance on relationships with a relatively small number of customers particularly in the United States, and our reliance on a diversification strategy to increase sales in other product areas.*

Contributions in 2012 from sales in the United States of our HPV test products represented approximately 12% of our total net sales. While the ultimate decision to order this test is made by physicians in consultation with their patients, in the U.S. the test analysis is generally performed by reference laboratories, who in turn are the customers of QIAGEN in terms of ordering tests and related equipment. At present, a limited number of reference laboratories in the U.S. account for the majority of HPV test sales. In times of economic hardship or high unemployment patients may decide to forego or delay

routine tests. Further, the cost of HPV testing in the U.S. is reimbursed to reference laboratories by insurance providers and health maintenance organizations. If these insurance plans decide to limit the availability of payments for our test to their members, it could have a significant adverse impact on our results of operations. Growth in other areas through diversification and new product launches has reduced the proportion of total net sales coming from HPV tests in the U.S., but if we fail to further diversify, we could be at risk that underperformance of the HPV line or loss of a customer could materially affect results of operations.

*We may encounter delays in receipt, or limits in the amount, of reimbursement approvals and public health funding, which will impact our ability to grow revenues in the healthcare market.*

Third-party payors are often reluctant to reimburse healthcare providers for the use of medical tests that involve new technologies or provide novel diagnostic information. In addition, third-party payors are increasingly limiting reimbursement coverage for medical diagnostic products and, in many instances, are exerting pressure on diagnostic product suppliers to reduce their prices. Since each third-party payor often makes reimbursement decisions on an individual patient basis, obtaining such approvals is a time-consuming and costly process that requires us to provide scientific and clinical data supporting the clinical benefits of each of our products. As a result, there can be no assurance that reimbursement approvals will be obtained. This process can delay the broad market introduction of new products, and could have a negative effect on our results of operations. As a result, third-party reimbursement may not be consistent or financially adequate to cover the cost of our products. This could limit our ability to sell our products or cause us to reduce prices, which would adversely affect our results of operations.

*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 organizations could have a significant adverse effect on demand for our products. Research and development budgets are affected by changes in available resources, the mergers of pharmaceutical and biotechnology companies, changes in spending priorities and institutional budgetary policies. Our results of operations

could be adversely affected by any significant decrease in expenditures for life sciences research and development by pharmaceutical and biotechnology companies, academic institutions, and government and private laboratories. In addition, short-term changes in administrative, regulatory or purchasing-related procedures can create uncertainties or other impediments that can have an adverse impact on our results of operations.

In recent years, the pharmaceutical and biotechnology industries have undergone substantial restructuring and consolidation. Additional mergers or consolidation within the pharmaceutical and biotechnology industries could cause us to lose existing customers and potential future customers, which could have a material adverse impact on our results of operations.

Approximately 25 % of our sales are generated from demand for our products used in the Academia customer class by researchers at universities, government laboratories and private foundations, and whose funding is dependent upon grants from government agencies, such as the U.S. National Institutes of Health (NIH). Although the level of research funding has been increasing in recent years, we cannot assure you that this trend will continue given federal and state budget constraints. Government funding of research and development is subject to the political process, which is inherently unpredictable. Future sales may be adversely affected if our customers delay purchases as a result of uncertainties regarding 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 government agencies in other countries that fund life sciences research and development activities. A reduction in government funding for the NIH or government research agencies in other countries could have a serious adverse impact on our results of operations.

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

We and our customers operate in a highly regulated environment characterized by continuous changes in the governing regulatory framework, particularly for product approvals. Genetic research activities and products commonly referred to as "genetically engineered" (such as certain food and therapeutic products) are subject to extensive governmental regu-

lation in most developed countries, especially in the major markets for pharmaceutical and diagnostic products such as the European Union, the U.S. and Japan. In recent years, several highly publicized scientific events (most notably in genomic research and "cloning") have prompted intense public debates on the ethical, philosophical and religious implications of an unlimited expansion in genetic research and the use of products emerging from this research. As a result of this debate, some key countries may increase existing regulatory barriers, which could adversely affect 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.

Changes in the existing regulations or adoption of new requirements or policies could adversely affect our ability to sell our approved products or to seek approvals for new products in other countries around the world. Sales of certain products now in development may be dependent upon us successfully conducting pre-clinical studies, clinical trials and other tasks required to gain regulatory approvals. These trials could be subject to extensive regulation by governmental authorities in the U.S., particularly the FDA, and regulatory agencies in other countries. These trials involve substantial uncertainties and could impact customer demand for our products.

In addition, certain products, especially those intended for use in in vitro diagnostic applications, require regulatory approvals in various countries. For example, since the European Union Directive 98/79/EC on in vitro diagnostic medical devices, or EU-IVD-D, went into effect in 2003, all products and kits used for in vitro diagnostic applications must be compliant with this directive. In addition to high-risk products such as HIV testing systems (list A of Annex II of the directive) or blood glucose testing systems (list B of Annex II of the directive), nucleic acid purification products, which are used in diagnostic workflows, are affected by this regulatory framework. The major goals of this directive are to standardize diagnostic procedures within the European Union, to increase reliability of diagnostic analysis and to enhance patient safety. If we fail to obtain any required clearance or approvals, it could significantly damage our business in these markets.

Several of our key products and programs are medical devices subject to extensive regulation by the FDA under the U.S. Food, Drug and Cosmetic Act. We plan to apply for FDA

clearance or approval of additional products in the future as medical devices. Regulatory agencies in other countries also have medical device approval regulations that are becoming more extensive. These regulations govern most commercial activities associated with medical devices, including indications for the use of these products as well as other aspects that include product development, testing, manufacturing, labeling, storage, recordkeeping, advertising and promotion. Compliance with these regulations is expensive and time-consuming.

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

We buy materials to create our products from a number of suppliers and are not dependent on any one supplier or group of suppliers for our business as a whole. However, key components of certain products, including certain instrumentation components and chemicals, are available only from a single source. If supplies from these vendors are delayed or interrupted for any reason, we may not be able to obtain these materials timely or in sufficient quantities or qualities in order to produce certain products, and this could have an adverse impact on our results of operations.

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

Our long-term business strategy involves entering into strategic alliances as well as marketing and distribution arrangements with academic, corporate and other partners relating to the development, commercialization, marketing and distribution of certain of our existing and potential products. We may be unable to continue to negotiate these collaborative arrangements on acceptable terms, and these relationships also may not be scientifically or commercially successful. In addition, we may be unable to maintain these relationships, and our collaborative partners may pursue or develop competing products or technologies, either on their own or in collaboration with others.

For example, our Personalized Healthcare business includes projects with pharmaceutical and biotechnology companies to co-develop companion diagnostics paired with drugs that those companies either market currently or are developing for future use. The success of these co-development programs, including regulatory approvals for the companion diagnostics, depends upon the continued commitment of our partners

to the development of those drugs, the outcome of clinical trials for the drugs and diagnostics, and regulatory approvals of the paired diagnostic tests and drugs. In addition, the future level of sales for companion diagnostics that we bring to market depends, in some measure, on the commercial success of the relevant drugs. More companion diagnostics would be sold in combination with a widely prescribed drug than a drug with limited use. Hence, the future success of these diagnostics depends on our Pharma partners' actions and commercial success.

*Some of our customers are requiring us to change our sales arrangements to lower their costs, and this may limit our pricing flexibility and harm our business.*

Some of our customers have developed purchasing initiatives to reduce the number of vendors from which they purchase products to lower their supply costs. In some cases, these customers have established agreements with large distributors, which include discounts and direct involvement in the distributor's purchasing process. These activities may force us to supply large distributors with our products at discounts in order to continue providing products to some customers. For similar reasons, many larger customers, including the U.S. government, have requested, and may request in the future, special pricing arrangements, which can include blanket purchase agreements. These agreements may limit our pricing flexibility, which could harm our business and affect our results of operations. For a limited number of customers, and at the customer's request, we have conducted sales transactions through third-party online intermediaries to whom we are required to pay commissions. If sales grow through these intermediaries, it could have an adverse impact on our results of operations, particularly a negative impact on our gross profit.

*We heavily rely on air cargo carriers and other overnight logistics services, and shipping delays or interruptions could harm our business.*

Our customers in the scientific research markets typically only keep a modest inventory of our products on hand, and consequently require overnight delivery of purchases. As a result, we heavily rely on air cargo carriers and logistic suppliers. If overnight services are suspended or delayed, and other delivery carriers and logistic suppliers cannot provide satisfactory services, customers may suspend a significant amount of their work. The lack of adequate delivery alternatives would have a serious adverse impact on our results of operations.

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

Our senior management consists of the Managing Directors and our most senior executives responsible for core functions, led by Mr. Peer Schatz, our Chief Executive Officer. The loss of Mr. Schatz could have a material adverse effect on our operations. Further, although we have not experienced any difficulties attracting or retaining key management and scientific staff, our ability to recruit and retain qualified, skilled employees will continue to be critical to our success. Given the intense competition for experienced scientists among pharmaceutical and biotechnology companies as well as academic and other research institutions, there can be no assurance that we will be able to attract and retain employees critical to our success on acceptable terms. Initiatives to expand QIAGEN will also require additional employees, including management with expertise in areas such as manufacturing and marketing, and the development of existing managers to lead a growing organization. The failure to recruit new employees, or develop existing employees, could have a material adverse impact on our results of operations.

*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 typically 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 quarter, in particular since it is during this period that they receive new information on both their budgets and requirements. As a result, even late in each quarter, we cannot predict with certainty whether our sales 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 customer purchasing trends during a quarter vary from historical patterns as may occur with changes in market conditions, our quarterly financial results could deviate significantly from our projections. As a result, our sales forecasts for any given quarter may prove not to have been accurate. We also may not have sufficient, timely information to confirm or revise our sales projections for a specific quarter.

*Changes in tax laws or their application could adversely affect our results of operations.*

Changes in tax laws or their application with respect to matters such as changes in tax rates, transfer pricing and income allocation, utilization of tax loss carry forwards, intercompany dividends, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, and changes to tax credit mechanisms, could increase our effective tax rate and adversely affect our results of operations. Additionally, changes in other laws, such as the U.S. health-care reform legislation that was signed into law in the U.S. in 2010, may subject us to additional excise taxes. The increased tax burden as a result of changes in law may adversely affect our results of operations.

*We have a significant amount of debt that may adversely affect our financial condition.*

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

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

At December 31, 2012, our consolidated balance sheet reflected approximately \$1.8 billion of goodwill and approximately \$853.9 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles (U.S. GAAP) require us to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment review often cannot be done at the level of the individual asset and it must instead be applied to a group of assets. For the purpose of our annual goodwill impairment testing based on the current circumstances of how we manage our business, this group of assets is the Company as a

whole. If we determine that any of our goodwill or intangible assets were impaired, we will be required to take an immediate charge to earnings and our results of operations could be adversely affected.

*Exchange rate fluctuations may adversely affect our business and operating results.*

Since we currently market our products 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 economically 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 future exchange rate fluctuations. While we may 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 strategic equity investments may result in losses.*

We have made, and may continue to make, strategic investments in businesses as opportunities arise. We periodically review the carrying value of these investments for impairment, considering factors that include 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, we could be required to write down the investment. This could result in future charges on our earnings that could materially adversely affect our results of operations. It is uncertain whether or not we will realize any long-term benefits from these strategic investments.

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

Our business involves operations in several countries outside of the U.S. Our consumable manufacturing facilities are located in Germany, China, France, the United Kingdom and the U.S., and our instrumentation facilities are located in Switzerland. We source raw materials and subcomponents to manufacture our products from different countries. We have established sales subsidiaries in numerous countries including the U.S., Germany, Japan, the United Kingdom, France, Switzerland, Australia, Canada, the Netherlands, Sweden, Italy, Hong Kong, Singapore, Turkey, South Korea, Taiwan, Malaysia, China, Spain, Brazil, Mexico, Russia and India. In addition, our products are sold through independent distributors serving more than 40 other countries. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. We have invested heavily in computerized information systems in order to manage more efficiently the widely dispersed components of our operations. If we fail to coordinate and manage these activities effectively, our business and results of operations will be adversely affected.

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

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

Our top seven emerging markets are Brazil, Russia, India, China, South Korea, Mexico and Turkey and we expect to continue to focus on expanding our business in these or other fast-growing markets. In addition to the currency and international operation risks described above, our international operations are subject to a variety of risks that include those

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

*Our global operations may be affected by actions of governments, global or regional economic developments, weather or transportation delays, natural disasters or other force majeure events (collectively, unforeseen events) which may negatively impact our suppliers, our customers or us.*

Our business involves operations around the world. Our consumable manufacturing facilities are located in Germany, China, France, the United Kingdom and the U.S., and our instrumentation facilities are located in Switzerland. We have established sales subsidiaries in numerous countries and our products are sold through independent distributors serving more than 40 additional countries. Our facilities may be harmed by unforeseen events, and in the event we or our customers are affected by a disaster, we may experience delays or reductions in sales or production, or increased costs, or may be required to identify alternate suppliers or rely on third-party manufacturers.

Our instrumentation manufacturing processes are dependent upon certain components provided by third-party suppliers located in Japan, which experienced a severe earthquake followed by a tsunami in March 2011. To the extent that our suppliers are impacted by a natural disaster or other disruption, we may experience periods of reduced production. Any unexpected interruptions in our production capabilities may lead to delayed or lost sales and may adversely affect our results of operations for the affected period.

In addition, to the extent we temporarily shut down any facility following such an unforeseen event, we may experience disruptions in our ability to ship products to customers or oth-

erwise operate our business as a result of the unforeseen event. While our global operations give us the ability to ship products from alternative sites, we may not be able to do so because our customers' facilities are shutdown or the local logistics infrastructure is not functioning, and our sales will suffer.

Damage to our property due to unforeseen events and the disruption of our business from casualties may be covered by insurance, but this insurance may not be sufficient to cover all of our potential losses and such insurance may not continue to be available to us on acceptable terms, or at all. In addition, we may incur incremental costs following an unforeseen event which will reduce profits and adversely affect our results of operations.

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

Our success depends 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, 2012, we owned 193 issued patents in the United States, 143 issued patents in Germany and 767 issued patents in other major industrialized countries. In addition, at December 31, 2012, we had 972 pending patent applications, and we intend to file applications for additional patents as our products and technologies are developed. The patent positions of technology-based companies 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 tends to lag behind actual discoveries by several months. Therefore, no assurance can be given that patents will issue from any patent applications that we own or license or if patents do issue, that the claims allowed will be sufficiently broad to protect our technology. In addition, no assurance can be given that any issued patents that we own or license will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide us competitive advantages. Further, as issued patents expire, we may lose some competitive advantage as others develop competing products and as a result, we may lose revenue.

*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 sample and assay technologies that are closely related to those we use. From time to time, we receive inquiries requesting confirmation that we do not infringe patents of third parties. We endeavor to follow developments in this field, and we do not believe that our technologies or products infringe any proprietary rights of third parties. However, there can be no assurance that third parties will not challenge our activities and, if so challenged, that we will prevail. In addition, the patent and proprietary rights of others 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 proceedings.

*Our business exposes us to potential product liability.*

The marketing and sale of our products and services for certain applications entail a potential risk of product liability. Although we are not currently subject to any material product liability claims, product liability claims may be brought against us in the future. 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 carry product liability insurance coverage, which is limited in scope and amount. There can be no assurance that we will be able to maintain this insurance at a reasonable cost and on reasonable terms, or that this insurance will be adequate to protect us against any or all potential claims or losses.

We are subject to various laws and regulations generally applicable to businesses in the different jurisdictions in which we operate, including laws and regulations applicable to the handling and disposal of hazardous substances. 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 impact on us.

## *Our operations have inherent IT risks.*

Business and production processes are increasingly dependent on information technology systems. Major disruptions or failure of global or regional business systems may result in the loss of data and/or impairment of business and production processes. QIAGEN has established a global IT organization with rules and regulations that define the relevant roles and responsibilities, and also works with external partners that provide certain operative IT functions. Technical precautions have been established together with our IT service providers to address this risk.

## Performance Review

### **Forward-looking and Cautionary Statements**

This report contains forward-looking statements that are subject to risks and uncertainties. These statements can be identified by the use of forward-looking terminology, such as "believe," "hope," "plan," "intend," "seek," "may," "will," "could," "should," "would," "expect," "anticipate," "estimate," "continue" or other similar words. 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, including, but not limited to, the following: risks associated with our expansion of operations, including the acquisition of new businesses; variability in our operating results from quarter to quarter; management of growth, international operations, and dependence on key personnel; intense competition; technological change; our ability to develop and protect proprietary products and technologies and to enter into and maintain collaborative commercial relationships; our future capital requirements; general economic conditions and capital market fluctuations; and uncertainties as to the extent of future government regulation of our business. As a result, our future success involves a high degree of risk. For further information, refer to the more specific risks and uncertainties discussed under the caption "Risk Factors" in Item 3 of the 2012 Annual Report on Form 20-F on file with the U.S. Securities and Exchange Commission and throughout this Annual Report.

## **Results of Operations**

### **Overview**

We are the world's leading provider of innovative Sample & Assay Technologies, based on independent market studies of United States and European market shares for our products and technologies. Our automated systems and consumable products empower customers to transform raw biological samples into valuable molecular information. Sample technologies are used to isolate DNA, RNA and proteins from any biological sample, such as blood or tissue. Assay technologies are then used to amplify, enrich and provide results for analysis of biomolecules, such as the DNA of a virus or a mutation of a gene.

We sell our products, sample and assay kits known as consumables and automated instrumentation systems using those technologies, to four major customer classes:

- **Molecular Diagnostics** – healthcare providers supporting many aspects of patient care including prevention, profiling of diseases, personalized healthcare and point of need testing
- **Applied Testing** – government or industry customers using molecular technologies in fields such as forensics, veterinary diagnostics and food safety testing
- **Pharma** – drug discovery and development efforts of pharmaceutical and biotechnology companies
- **Academia** – researchers exploring the secrets of life such as the mechanisms and pathways of diseases, and in some cases translating that research into drug targets or commercial applications

We market products in more than 100 countries throughout the world. We have established subsidiaries in markets we believe have the greatest sales potential, including countries throughout Europe, Asia, the Americas and Australia. We also work with specialized independent distributors and importers. As of December 31, 2012, we employed approximately 4,000 people in more than 35 locations worldwide.

In 2012, operating income on a consolidated basis was \$169.8 million, a 71% increase from \$99.6 million in 2011, which in turn was a 47% decline compared from \$188.5 million in 2010. The 2011 decline was due to the impact of a restructuring-related charge in the fourth quarter of 2011.

We have delivered five-year compound annual growth rates of approximately 14% in net sales and 21% in net income through 2012, as reported under U.S. GAAP. We have funded our growth through internally generated funds, debt, and private and public sales of equity securities.

### **Recent Acquisitions**

We have made a number of strategic acquisitions since 2010, expanding our technology and product offerings as well as extending our geographic presence. These transactions include:

- In June 2012, we unveiled an initiative to enter the NGS market, including our early 2012 acquisition of Intelligent Bio-Systems, Inc., which added important expertise and innovative technologies in this emerging field. Our NGS initiative aims to expand next-generation sequencing technologies from the current focus on life science research into routine use in clinical research and molecular diagnostics. The expected sample-to-result workflows will incorporate a next-generation benchtop sequencer, our QIAcube and QIASymphony automation platforms, leading sample preparation solutions, specialized gene panels and GeneGlobe ([www.geneglobe.com](http://www.geneglobe.com)) portfolio of more than 60,000 well-defined and characterized molecular assays. New bioinformatics, including NGS solutions from a new collaboration with SAP AG, will handle clinical data produced in next-generation sequencing. Our new NGS platform is expected to be phased into the market beginning in 2013.
- In May 2012, we acquired AmniSure International LLC, including the AmniSure® assay for determining whether a pregnant woman is suffering rupture of fetal membranes (ROM), a widespread cause of premature delivery and neonatal complications. This product, which is approved in the U.S. and many other markets, is expected to be catalytic for our Point of Need portfolio.
- In August 2011, we acquired Cellectis Ltd., an Australian company that created the proprietary "pre-molecular" QuantiFERON® technology. The early-warning QuantiFERON®-TB Gold test, which detects latent tuberculosis (TB) infection as a strategy for the prevention of active TB disease in vulnerable populations, has become an important growth driver in 2012. Also in 2012, we submitted the QuantiFERON®-CMV test to the FDA for use in diagnosing cytomegalovirus (CMV).
- In July 2011, we purchased a majority of the shares of Ipsogen S.A., a publicly listed French company that is a global leader in molecular profiling and personalized healthcare diagnostics for a broad range of blood cancers. Through a public tender offer for the remaining shares, we had acquired 89% of the shares of Ipsogen by year-end 2012. We intend to fully acquire Ipsogen through future public offers. Effective January 1, 2013, Ipsogen was renamed QIAGEN Marseille and its sales and distribution networks were integrated with our commercial operations.
- In January 2010, we acquired ESE GmbH, now QIAGEN Lake Constance GmbH, a German developer and manufacturer of portable, battery-operated, "ultra-fast time to result" multiplex UV and fluorescence optical measurement devices. ESE's systems for point of need testing in healthcare and applied testing enable low-throughput molecular testing in physician practices, emergency rooms, remote field areas, and other settings where a laboratory infrastructure is not accessible and fast turnaround is required.

Our financial results include the contributions of our recent acquisitions from the date of acquisition, as well as costs related to the acquisitions and integrations of the acquired companies, such as the relocation and closure of certain facilities.

We determined that we operate as one business segment in accordance with ASC Topic 280, Segment Reporting. Our chief operating decision maker (CODM) makes decisions on business operations and resource allocation based on evaluations of the QIAGEN Group as a whole. With revenues derived from our entire product and service offerings, it is not practicable to provide a detail of revenues for each group of similar products and services or for each customer group, as full discrete financial information is not available. Considering the acquisitions made during 2012, we determined that we still operate as one business segment. However, we do provide certain revenue information by customer class to allow better insight into our operations. This information is estimated using certain assumptions to allocate revenue among the customer classes.

## **Year Ended December 31, 2012, Compared to 2011**

### **Net Sales**

In 2012, net sales increased 7% to \$1.25 billion compared to \$1.17 billion in 2011. This increase in net sales was driven by business expansion in all customer classes – particularly Molecular Diagnostics and Applied Testing – and all geographic regions. Contributions from the acquisitions of Ipsogen (until July 2012), Cellectis (until August 2012) and AmniSure (acquired in May 2012) provided six percentage points of total growth, and the rest of our portfolio provided four percentage points. Currency movements had a negative impact of three percentage points on reported sales growth. In 2012, consumable and related revenues, which represent approximately 86% of total sales, increased 7% as compared to 2011. Sales of instrumentation products, which represent 14% of net sales, increased 7% in 2012. Instrument sales benefited during 2012 from demand for a broad range of QIAGEN instruments. We exceeded our 2012 goal for more than 200 new placements of the QIAxSymphony automation platform, reaching an installed base of more than 750 platforms. Approximately 70% of total QIAxSymphony placements as of the end of 2012 have been with Molecular Diagnostics customers, primarily through reagent rental agreements where revenues are recognized over a multiyear period. Demand also has been strong among Applied Testing customers.

The Asia-Pacific / Japan region (+14% growth, 19% of sales) grew at a robust pace in 2012 on improving demand in China, Japan and our top emerging markets which include India and Korea. Results in the Europe / Middle East / Africa region (+2% growth, 34% of sales) advanced on higher sales in northern European countries and growth in all customer classes. The Americas (+8% growth, 46% of sales) rose on higher contributions from Molecular Diagnostics and Applied Testing, more than offsetting lower HPV sales in the region.

In Molecular Diagnostics, which represents approximately 49% of net sales, we achieved an increase of 13% of net sales in 2012 compared to 2011. Healthcare-related sales advanced in 2012, driven by new products and solid demand for instruments, particularly the QIAxSymphony automation platform. In Prevention, the QuantiFERON-TB test (acquired with Cellectis in 2011) achieved growth in 2012 on initiatives in the U.S. and Europe to drive greater use of this new test for latent tuberculosis (TB). Full-year 2012 sales of products used in HPV testing performed in line with expectations, as steady volumes in the U.S. were more than offset by pricing pressure from the implementation of multiyear customer agreements.

Personalized Healthcare delivered ongoing strong growth on global demand for the *therascreen* portfolio of companion diagnostic kits – particularly the KRAS test launched in mid-2012 after FDA approval for use in metastatic colorectal cancer patients – as well as higher revenues from co-development projects with pharmaceutical companies. In Point of Need, the AmniSure assay for premature rupture of fetal membranes in pregnant women provided important contributions after its acquisition in May 2012.

In Applied Testing, which represents approximately 8% of net sales, we achieved 19% growth in 2012 compared to 2011, primarily on strong demand for consumables used in human identification / forensics, veterinary medicine and food safety. Instrument sales also advanced in 2012, particularly following the early 2012 launch of assays for use on the QIAxSymphony automation platform.

In Pharma, which represents approximately 19% of net sales, we experienced 3% growth in 2012 compared to 2011, led by demand for products used in oncology research as well as the GeneGlobe portfolio. Also contributing to the growth was ongoing expansion of Cortal products used on QIAxSymphony for quality control in biopharmaceutical processing. However, growth rates were slower in the second half of 2012 as restructuring activities at some pharmaceutical companies impacted results.

In Academia, which represents approximately 24% of net sales, we experienced a 2% decline in 2012 compared to 2011 primarily due to currency movements. Concerns about future U.S. and European government funding for life sciences research prompted very cautious spending patterns among some customers in the U.S. and Europe in the fourth quarter of 2012. Funding uncertainties in these regions are expected to continue in 2013.

### **Gross Profit**

Gross profit was \$824.0 million, or 66% of net sales, in 2012, compared to \$749.8 million, or 64% of net sales, in 2011. Generally, our consumable sample and assay products have a higher gross margin than our instrumentation products and service arrangements. Fluctuations in the sales levels of these products and services can result in fluctuations in gross margin between periods. An increase in milestone payments from companion diagnostic co-development arrangements in 2011 negatively affected the 2011 margin since the gross margin on these services is significantly below the margin on product sales. Gross margin in 2011 also was negatively

impacted by costs related to the relocation of production facilities, including moving into newly constructed production space in Hilden, Germany; costs incurred following the Japanese earthquake and other natural disasters; and costs related to the restructuring announced late in 2011.

Amortization expense related to developed technology and patent and license rights acquired in a business combination is included in cost of sales. The amortization expense on acquisition-related intangibles within cost of sales increased to \$78.5 million in 2012 from \$70.2 million in 2011, as a result of an increase in intangibles acquired in recent business combinations. We expect our acquisition-related intangible amortization to continue to increase as a result of acquisitions.

During 2012, a total of \$3.1 million was expensed to acquisition and restructuring-related cost of sales. These costs included costs related to the relocation of production facilities as well as the write-up of acquired inventory to fair market value as a result of business combinations. In accordance with purchase accounting rules, acquired inventory was written up to fair market value and subsequently expensed as the inventory was sold. Additionally, we recorded reversals of \$6.7 million related to changes in the fair value of contingent consideration and \$4.6 million related to acquired contingent liabilities.

During 2011, a total of \$9.6 million was expensed to acquisition and restructuring-related cost of sales. These costs included costs related to the relocation of production facilities as well as the write-up of acquired inventory to fair market value as a result of business combinations.

#### **Research and Development**

Research and development expenses decreased by 6% to \$122.5 million (10% of net sales) in 2012, compared to \$130.6 million (11% of net sales) in 2011. The decline was partially due to a refocusing of our portfolio of development projects in early 2012. Research and development expense was also positively affected by \$5.8 million of currency exchange impact in 2012. As we continue to discover, develop and acquire new products and technologies, we expect to incur additional expenses related to facilities, licenses and employees engaged in research and development efforts. Additionally, research and development costs are expected to increase as a result of seeking regulatory approvals, including U.S. FDA Pre-Market Approval (PMA), U.S. FDA 510(k) clearance and EU CE approval of certain assays or instru-

ments. We have a strong commitment to innovation and expect to continue to make investments in our research and development efforts.

#### **Sales and Marketing**

Sales and marketing expenses increased 12% to \$343.5 million (27% of net sales) in 2012 from \$307.3 million (26% of net sales) in 2011. The increase in sales and marketing expenses reflects the acquisitions in 2012 along with increased sales and marketing investments to globalize the acquired Cellestis and Ipsogen product portfolios. The increase was partially offset by \$10.2 million of favorable currency exchange impact in 2012. Sales and marketing expenses are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses and other promotional expenses. In addition, the sales and marketing expenses include the costs of maintaining separate sales organizations addressing customers in Molecular Diagnostics, Applied Testing, Pharma and Academia. We anticipate that sales and marketing costs will continue to increase along with new product introductions and growth in sales of our products, but we expect sales and marketing costs will grow at a slower rate than our overall revenue growth over the long term.

Starting January 1, 2013, the United States began imposing a 2.3% excise tax on the sale, including leases, of any "taxable medical device," that is any FDA-regulated device intended for human use, under the U.S. healthcare reform laws enacted in 2010. Based on our estimate of product revenue that is expected to be subject to the regulations, we currently expect that imposition of the tax will cost up to \$6.0 million annually in 2013 and will be recorded as a selling expense.

#### **General and Administrative, Restructuring, Integration and Other**

General and administrative, business integration, restructuring and related costs decreased by 18% to \$152.1 million (12% of net sales) in 2012 from \$185.5 million (16% of net sales) in 2011. The net decrease is due primarily to the restructuring measures that started in late 2011 to streamline the organization. We expensed \$41.0 million and \$69.4 million in 2012 and 2011, respectively, to general and administrative restructuring costs related to internal restructuring of subsidiaries, including severance and retention costs. The restructuring costs primarily relate to a project we began in late 2011 to enhance productivity by streamlining the organization and freeing up resources for reallocation to strategic initiatives to help drive growth and innovation, strengthen our

industry leadership position and improve longer-term profitability. This project was focused to eliminate organizational layers and overlapping structures, actions that will enhance our processes, speed and productivity. Additionally, general and administrative, integration and related costs decreased by \$6.2 million due to currency impact in 2012, compared to the same period of 2011. During 2012, we incurred acquisition costs of approximately \$4.5 million, primarily in connection with the acquisitions of AmniSure and Intelligent Bio-Systems. In connection with the integration of the acquired companies, we aim to improve efficiency in general and administrative operations. As we further integrate the acquired companies and pursue other opportunities to gain efficiencies, we expect to continue to incur additional business integration and restructuring costs in 2013. Over time, we believe the integration and restructuring activities will reduce general and administrative expenses as we improve efficiency in general and administrative operations.

#### **Acquisition-Related Intangible Amortization**

Amortization expense related to developed technology and patent and license rights acquired in a business combination is included in cost of sales. Amortization of trademarks and customer base acquired in a business combination is recorded in operating expense under the caption "acquisition-related intangible amortization." Amortization expenses of intangible assets not acquired in a business combination are recorded within cost of sales, research and development, or sales and marketing line items based on the use of the asset.

During 2012, amortization expense on acquisition-related intangibles within operating expense increased to \$36.1 million, compared to \$26.7 million in 2011. The increase in expense is the result of an increase in amortized intangibles acquired in our recent business combinations. We expect acquisition-related intangible amortization to continue to increase as a result of our acquisitions.

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

Other expense was \$24.7 million in 2012, compared to \$3.4 million in 2011. The increase in total other expense in 2012 was primarily the result of higher foreign currency losses and decreased interest income partially offset by lower interest expense and higher income from equity method investees.

For the year ended December 31, 2012, interest income decreased to \$2.4 million from \$6.1 million in 2011. The decrease in interest income was primarily due to lower short-term investment balances during the first half of 2012.

Interest expense decreased to \$23.5 million in 2012, compared to \$25.4 million in 2011. Interest costs primarily relate to debt, discussed in Note 15 in the accompanying notes to the consolidated financial statements. The decrease in interest expense is primarily due to a lower average outstanding debt balance following repayments of \$469.9 million in 2011.

For the year ended December 31, 2012, foreign currency losses of \$7.2 million were realized compared to a gain of \$12.4 million in 2011. The currency gain in 2011 includes a favorable currency fluctuation in related to the funding of the Cellectis acquisition.

#### **Provision for Income Taxes**

In 2012 and 2011, our effective tax rates were 11% and 1%, respectively. Our operating subsidiaries are exposed to effective tax rates ranging from zero up to more than 40%. Fluctuations in the distribution of pre-tax income among our operating subsidiaries can lead to fluctuations of the effective tax rate in the consolidated financial statements. Our effective tax rate in 2012 reflects the impacts of business and financing restructurings implemented during 2011 and 2012. The effective tax rate for 2011 includes the effect of restructuring costs related to our transformation project, including impairments that lowered the mix of earnings in our higher taxing jurisdictions.

#### **Foreign Currencies**

QIAGEN N.V.'s reporting currency is the U.S. dollar, and most of our subsidiaries' functional currencies are the local currencies of the countries in which they are headquartered. All amounts in the financial statements of entities whose functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows: (1) assets and liabilities at period-end rates, (2) income statement accounts at average exchange rates for the period, and (3) components of shareholders' equity at historical rates. Translation gains or losses are recorded in shareholders' equity, and transaction gains and losses are reflected in net income. The net (loss) gain on foreign currency transactions in 2012, 2011 and 2010 was \$(7.2) million, \$12.4 million, and \$2.6 million, respectively, and is included in other income (expense), net.

#### **Derivatives and Hedging**

In the ordinary course of business, we use derivative instruments, including swaps, forwards and / or options, to manage potential losses from foreign currency exposures and variable-rate debt. The principal objective of such derivative

instruments is to minimize the risks and / or costs associated with global financial and operating activities. We do not utilize derivative or other financial instruments for trading or other speculative purposes. All derivatives are recognized as either assets or liabilities in the balance sheet and are measured at fair value with any change in fair value recognized in earnings in the period of change, unless the derivative qualifies as an effective hedge that offsets certain exposures. In determining fair value, we consider both the counterparty credit risk and our own creditworthiness. To determine our own credit risk we estimate our own credit rating by benchmarking the price of our outstanding debt to publicly available comparable data from rated companies. Using the estimated rating, we quantify our credit risk by reference to publicly traded debt with a corresponding rating.

**Foreign Currency Derivatives.** As a globally active enterprise, we are subject to risks associated with fluctuations in foreign currencies in our ordinary operations. This includes foreign currency-denominated receivables, payables, debt and other balance sheet positions, including intercompany items. We manage our balance sheet exposure on a group-wide basis primarily using foreign exchange forward contracts.

**Interest Rate Derivatives.** We have used interest rate derivative contracts on certain borrowing transactions to hedge fluctuating interest rates. We entered into interest rate swaps in which we agreed to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional principal amount. The interest swaps matured in 2011.

We make use of 'economic hedges' – i. e., derivatives that do not have a formally designated hedging relationship – as well as 'accounting hedges.' All derivatives that qualify for hedge accounting are 'cash flow hedges.' Further details of our derivative and hedging activities can be found in Note 13 to the accompanying consolidated financial statements.

### Foreign Currency Exchange Rate Risk

As a global enterprise, we are subject to risks associated with fluctuations in foreign currencies with regard to our ordinary operations. This includes foreign currency-denominated receivables, payables, debt, and other balance sheet positions as well as future cash flows resulting from anticipated transactions including intra-group transactions.

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, Chinese renminbi, Swiss franc, 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. In general terms, depreciation of the U.S. dollar against our other foreign currencies will increase reported net sales. However, this effect is, at least partially, offset by the fact that we also incur substantial expenses in foreign currencies.

We have significant production and manufacturing facilities located in Germany and Switzerland, and intercompany sales of inventory also 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. We use an in-house bank approach to net and settle intercompany payables and receivables as well as intercompany foreign exchanged swaps and forward contracts in order to centralize the foreign exchange rate risk to the extent possible. We have entered in the past and may enter in the future into foreign exchange derivatives including forwards, swaps and options to manage the remaining foreign exchange exposure.

### Interest Rate Risk

At December 31, 2012, we had \$394.0 million in cash and cash equivalents as well as \$90.5 million in short-term investments. Interest income earned on our cash investments is affected by changes in the relative levels of market interest rates. We only invest in high-grade investment instruments. A hypothetical adverse 10% movement in market interest rates would not have materially impacted our financial statements.

Borrowings against lines of credit are at variable interest rates. We had no amounts outstanding against our lines of credit at December 31, 2012. A hypothetical adverse 10% movement in market interest rates would not have materially impacted our financial statements.

At December 31, 2012, we had \$ 847.0 million in long-term debt, none of which is at a variable rate. A hypothetical adverse 10% movement in market interest rates would not have materially impacted our financial statements.

### Liquidity and Capital Resources

To date, we have funded our business primarily through internally generated funds, debt, and private and public sales of equity. Our primary use of cash has been to support continuing operations and our capital expenditure requirements including construction of new facilities and acquisitions. As of December 31, 2012 and 2011, we had cash and cash equivalents of \$394.0 million and \$221.1 million, respectively. We also had short-term investments of \$90.5 million at December 31, 2012. Cash and cash equivalents are primarily held in U.S. dollars and euros, other than those cash balances maintained in the local currency of subsidiaries to meet local working capital needs. At December 31, 2012, cash and cash equivalents had increased by \$172.9 million from December 31, 2011, primarily as a result of cash provided by operating activities of \$244.9 million and financing activities of \$226.6 million partially offset by cash used in investing activities of \$300.9 million. As of December 31, 2012 and 2011, we had working capital of \$725.8 million and \$293.8 million, respectively.

**Operating Activities.** For the years ended December 31, 2012 and 2011, we generated net cash from operating activities of \$244.9 million and \$244.8 million, respectively. While net income of \$129.5 million in 2012 increased by \$34.6 million as compared to the prior year, 2011 net income was reduced by restructuring accruals which were mostly paid out in 2012. The non-cash components such as depreciation and amortization, share-based compensation, deferred income taxes and other non-cash activity including restructuring measures increased cash from operating activities by \$199.2 million as of December 31, 2012. This increase was partially offset by net changes in operating assets and liabilities of \$83.9 million, primarily due to an increase in inventories, accounts receivable and income taxes. Because we rely heavily on cash generated from operating activities to fund our business, a decrease in demand for our products, longer collection cycles or significant technological advances of competitors would have a negative impact on our liquidity.

**Investing Activities.** Approximately \$300.9 million of cash was used in investing activities during 2012, compared to \$540.3 million during 2011. Investing activities during 2012 consisted principally of \$39.9 million invested in short-term

investments, \$102.0 million in cash paid for purchases of property and equipment, primarily in our ongoing construction projects in the U.S., as well as \$26.1 million paid for intangible assets. Cash paid for acquisitions, net of cash acquired, of \$132.0 million was used primarily in the acquisitions of AmniSure and Intelligent Bio-Systems and includes \$1.1 million of cash paid in connection with acquisition milestone achievements. As of December 31, 2012, we also had made an investments of \$8.2 million in privately held companies. These investing activities were partially offset by \$6.0 million from the sale of short-term investments.

In 2009, we purchased the land and building adjacent to our facility in Hilden, Germany, for €2.5 million (approximately \$3.2 million) to further expand our German facilities for research and development and production. In addition, we started the expansion of our Germantown, Maryland, USA facility for production and administrative space in June 2010. While the construction in Germany is complete, the U.S. expansion projects are expected to continue into 2013, with both projects at an estimated total cost of approximately \$94.0 million. We anticipate that we will be able to fund these expansions with cash generated by operating activities.

In connection with certain acquisitions, we could be required to make additional contingent cash payments totaling up to \$134.2 million based on the achievement of certain revenue and operating results milestones as follows: \$18.9 million in 2013, \$23.4 million in 2014, \$16.3 million in 2015, \$17.5 million in 2016, \$7.0 million in 2017 and \$51.1 million payable in any 12-month period from now until 2017 based on the accomplishment of certain revenue targets, the launch of certain products or the grant of certain patent rights. Of the \$134.2 million total contingent obligation, approximately \$19.0 million is accrued as of December 31, 2012.

**Financing Activities.** Financing activities provided \$226.6 million in cash for the year ended December 31, 2012 compared to a use of \$310.6 million for 2011. Cash provided during 2012 was primarily due to new debt of \$400.0 million issued in a private placement of new senior unsecured notes. The new borrowings were used in part to repay \$143.3 million of short-term debt. Also in 2012, we commenced a share buyback and as of December 31, 2012 had repurchased 1.9 million common shares at a total price of approximately \$35.7 million. Other cash payments of \$6.0 million were related to milestone payments from previous acquisitions.

In December 2011, we entered into a €400.0 million syndicated multi-currency revolving credit facility expiring December 2016 of which no amounts were utilized at December 31, 2012. We have additional credit lines totaling €38.0 million with no expiration date, none of which was utilized as of December 31, 2012. We also have capital lease obligations, including interest, in the aggregate amount of \$22.8 million, and carry \$847.0 million of long-term debt, of which \$0.9 million is current as of December 31, 2012.

We have notes payable, which are the long-term borrowings of the proceeds from the issuances of \$150.0 million senior unsubordinated convertible notes, with a 1.5% coupon due in 2024 through QIAGEN Finance (2004 Notes), and of \$300.0 million 3.25% senior convertible notes (2006 Notes) due in 2026 through QIAGEN Euro Finance. QIAGEN Finance and Euro Finance are unconsolidated subsidiaries, which were established for this purpose. The 2004 Notes are convertible into our common shares at a conversion price of \$12.6449, subject to adjustment, and the 2006 Notes are convertible into our common shares at a conversion price of \$20.00, subject to adjustment. In connection with conversion of \$5.0 million of the 2004 Notes, we repaid \$5.0 million of the debt to QIAGEN Finance. At December 31, 2012, \$145.0 million and \$300.0 million are included in long-term debt for the amount of the notes payable to QIAGEN Finance and Euro Finance, respectively. The \$145.0 million note payable has an effective rate of 1.8%, and had an original maturity in July 2011. We refinanced the \$145.0 million note, which has a new maturity date of February 2024. The \$300.0 million note payable has an effective rate of 3.7% and is due in May 2026. QIAGEN N.V. has guaranteed the 2004 and 2006 Notes and has agreements with QIAGEN Finance and Euro Finance to issue shares to the investors in the event of conversion. These subscription rights, along with the related receivable, are recorded at fair value in the equity of QIAGEN N.V. as paid-in capital.

In October 2012, we completed a private placement through the issuance of new senior unsecured notes at a total amount of \$400 million with a weighted average interest rate of 3.66% (settled on October 16, 2012). The notes were issued in three series: (1) \$73 million 7-year term due in 2019 (3.19%); (2) \$300 million 10-year term due in 2022 (3.75%); and (3) \$27 million 12-year term due in 2024 (3.90%). Approximately €170 million (approximately \$220 million) of proceeds from the notes were used to repay amounts outstanding under our short-term revolving credit facility. The

remainder of the proceeds provides additional resources to support QIAGEN's longer-term business expansion.

Our Supervisory Board and shareholders granted management the discretion to repurchase up to \$100 million of our common shares (excluding transaction costs). In October 2012, we commenced the buyback and as of December 31, 2012 have repurchased 1.9 million common shares at a total price of approximately \$35.7 million. We expect to complete the share repurchase program during the first quarter of 2013.

We expect that cash from financing activities will continue to be impacted by issuances of our common shares in connection with our equity compensation plans and that the market performance of our stock will impact the timing and volume of the issuances. Additionally, we may make future acquisitions or investments requiring cash payments, the issuance of additional equity or debt financing.

We believe that funds from operations, existing cash and cash equivalents, together with the proceeds from our public and private sales of equity, and availability of financing facilities, will be sufficient to fund our planned operations and expansion during the coming year. However, the global economic downturn may have a greater impact on our business than currently expected, and we may experience a decrease in the sales of our products, which could impact our ability to generate cash. The availability of debt financing has also been negatively impacted by the global credit crisis. If our future cash flows from operations and other capital resources are not adequate to fund our liquidity needs, we may be required to obtain additional debt or equity financing or to reduce or delay our capital expenditures, acquisitions or research and development projects. If we could not obtain financing on a timely basis or at satisfactory terms, or implement timely reductions in our expenditures, our business could be adversely affected.

### **Off-Balance Sheet Arrangements**

Other than our arrangements with QIAGEN Finance and Euro Finance as discussed above and in the notes to the consolidated financial statements, we did not use special purpose entities and do not have off-balance sheet financing arrangements as of and during the years ended December 31, 2012, 2011 and 2010.

## Contractual Obligations

As of December 31, 2012, our future contractual cash obligations, including interest, are as follows:

### Contractual Obligations

	Total	2013	2014	2015	2016	2017	Payments Due by Period Thereafter
<b>\$ 1,000</b>							
Long-term debt	1,166,591	29,179	28,653	28,932	28,312	28,340	1,023,175
Capital lease obligations	22,846	5,396	5,304	5,290	3,998	1,429	1,429
Operating leases	54,454	16,309	11,389	9,834	5,879	3,234	7,809
Purchase obligations	60,369	54,754	4,124	1,339	152	—	—
License and royalty payments	21,261	9,224	3,762	1,773	1,798	1,799	2,905
<b>Total contractual cash obligations</b>	<b>1,325,521</b>	<b>114,862</b>	<b>53,232</b>	<b>47,168</b>	<b>40,139</b>	<b>34,802</b>	<b>1,035,318</b>

In addition to the above and pursuant to purchase agreements for several of our recent acquisitions, we could be required to make additional contingent cash payments totaling up to \$ 134.2 million based on the achievement of certain revenue and operating results milestones as follows: \$ 18.9 million in 2013, \$ 23.4 million in 2014, \$ 16.3 million in 2015, \$ 17.5 million in 2016, \$ 7.0 million in 2017, and \$ 51.1 million, payable in any 12-month period from now until 2017 based on the accomplishment of certain revenue targets, the launch of certain products or the grant of certain patent rights. As of December 31, 2012, we have accrued \$ 19.0 million.

Liabilities associated with uncertain tax positions, including interest and penalties, are currently estimated at \$ 13.8 million and are not included in the table above, as we cannot

reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

### Share Repurchase Program

The following table sets out information concerning repurchases of our common shares, which we intend to use to serve our exchangeable debt instruments and employee share-based remuneration plans. The approximate dollar value of shares that may yet be purchased under this program as of December 31, 2012 was \$ 64.3 million.

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly	(d) Approximate Dollar Value of Shares that May Yet Be Purchased
October 10/1/2012-10/31/2012	544,242	\$ 18.62	544,242	\$ 89,864,000
November 1/1/2012-11/30/2012	619,459	\$ 18.21	619,459	\$ 78,586,000
December 12/1/2012-12/31/2012	779,090	\$ 18.28	779,090	\$ 64,347,000
<b>Total</b>	<b>1,942,791</b>	<b>\$ 18.35</b>	<b>1,942,791</b>	

Purchases between October 1, 2012 and December 31, 2012 were made in accordance with the authorization to acquire and use treasury shares granted at the Annual General Meeting of Shareholders on June 27, 2012, pursuant to which the Managing Board was authorized to acquire up to \$100 million of QIAGEN common shares.

Since December 31, 2012, and through February 22, 2013, we repurchased 1.9 million shares under the share repurchase program for approximately \$38.5 million in total.

### **Dividend**

QIAGEN has not paid a cash dividend since its inception and does not intend to pay any dividends in the foreseeable future. We intend to retain any earnings for the development of our business.

### **Credit Rating**

QIAGEN is currently not rated by any credit rating agency.

## **Human Resources**

### **Overview**

The skills, knowledge, dedication and passion of our employees are critical for the success of QIAGEN. We want to recruit, support and retain the best employees, offering performance-based remuneration, development opportunities and measures to balance work and family life. We are committed to diversity in our teams that reflect the various backgrounds of our business partners. At the end of 2012, QIAGEN had 3,999 full-time equivalent employees, a 2% increase from 3,938 at the end of 2011. Total personnel expenses in 2012 were \$364 million compared to \$347 million in 2011.

### **Code of Ethics**

QIAGEN has in place a Code of Conduct which qualifies as a code of ethics, as required by SEC and NASDAQ Marketplace Rules. The Code of Conduct applies to all of QIAGEN's employees, including our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. The full text of the Code of Conduct is available on our website at [www.qiagen.com](http://www.qiagen.com).

### **Training and Retention**

At QIAGEN, we recognize that employees are our most important resource. Their exceptional talent, skill, and passion are key to our long-term success and corporate value. Employee development is therefore viewed as an integral success factor in creating lasting value for our customers, patients, colleagues, partners, and shareholders. QIAGEN has established a global Performance Enhancement System (PES) that creates a clear framework for regular, one-on-one review sessions in which managers discuss career development topics with each of their employees. These sessions include discussions of goals and their achievement, training needs and interests, career planning, organizational development, and the results of regularly performed "180° surveys." Professional Training and Development at QIAGEN is an ongoing process reaching all employees, which cycles from PES to participation, review, follow-up, and back to PES.

### **Management Campus (MC)**

This program, which is composed of two components, is designed to ensure the ongoing development of QIAGEN's future management generations. MC I accelerates the careers of our professionals by providing insights into major management topics while focusing on individual development and

## Employees

Region	Research & Development	Sales	Production	Marketing	Administration	Total
Americas	139	553	219	60	123	1,094
Europe	478	585	695	168	240	2,166
Asia Pacific & Rest of World	53	462	86	61	77	739
December 31, 2012	670	1,600	1,000	289	440	3,999

## Employees 2003 - 2012

	2012	2011	2010	2009	2008	2007	2006	2005	2004	2003
<b>Total</b>	<b>3,999</b>	<b>3,938</b>	<b>3,587</b>	<b>3,495</b>	<b>3,041</b>	<b>2,662</b>	<b>1,954</b>	<b>1,589</b>	<b>1,322</b>	<b>1,553</b>

business-related innovative actions. MC II is a senior executive program that is designed to invest in skill sets of QIAGEN's senior managers.

### QIAGEN Executive MBA Program

To support our future growth, QIAGEN offers employees the opportunity to participate in the QIAGEN Executive MBA Business Integration Program in cooperation with the University of Würzburg, Germany. The program provides professionals with a wide range of management skills and knowledge, which are key to an executive career in the industry and at QIAGEN in particular. Participants study in an international environment with colleagues from around the world. Two modules are conducted with partner universities in the U.S.: at Boston University in Boston, Massachusetts, and at Florida Gulf Coast University in Fort Myers, Florida.

### Compensation System

Since the creation of QIAGEN, management has formed a culture that seeks to attract and retain the best talent worldwide and reward associates for their performance. This compensation system aims to foster focus on achieving corporate strategic initiatives as well as personal accountability.

It is critical for QIAGEN to offer attractive compensation packages on a global basis. According to the QIAGEN philosophy, an employee who achieves their performance objectives should generally be awarded compensation comparable to the median levels of compensation provided by relevant benchmark companies. QIAGEN participates in various compensation benchmarking surveys that provide information on

the level, as well as the mix, of compensation awarded by various companies and industries for a broad range of positions around the world. In the case of QIAGEN, these include many peer life science and diagnostic companies based in the U.S.

QIAGEN has a "pay for performance" culture, with the compensation of employees linked to the achievement of corporate financial and individual performance goals. Business goals are established by the senior management. These goals are set at ambitious levels each year to motivate and drive performance, with a focus on both short-term and long-term quantifiable objectives. Performance metrics used for these goals include the achievement of targets for net sales, adjusted operating income and free cash flow. In 2012, the payments for short-term variable compensation were based on 91% achievement of the business goals.

Compensation for a significant majority of employees worldwide includes fixed base compensation and benefits, which vary according to local market customs, as well as a short-term variable cash bonus. The level of fixed compensation is paid in cash, usually on a monthly basis, and is designed to provide the employee with a reasonable standard of living relative to the compensation offered by peer companies. The amount of short-term variable cash bonus is designed to reward performance, with the payout amount based on the achievement of overall corporate financial results as well as individual performance against a written set of objectives. In the case of the Managing Board members, the maximum individual bonus is equivalent to 40% of the annual fixed salary.

Furthermore, to align our compensation programs with the interests of shareholders, senior executives receive a portion of their total compensation in the form of long-term compensation, which is granted as equity as a reward for performance. These grants are determined on an individual basis and approved by the Compensation Committee. These equity grants are predominantly made in the form of Restricted Stock Units (RSUs) with a staggered vesting period typically over three (43%), five (53%) and 10 years (13%) and stock options, which have a staggered vesting period typically over three years.

### **Work-Life Balance**

QIAGEN introduced services to help employees balance their personal life with our dynamic and driven work environment, including in-house corporate childcare and sabbatical programs, as well as company-sponsored fitness and health facilities, and programs. Flexible working hours apply to all employees except for functions that require on-time presence.

### **Workplace Health**

In today's business climate, the health of employees is often directly related to the health of the company. Increased job satisfaction, improved morale, reduced injuries, and increased productivity are just some of the benefits which a healthy work environment can have. At its headquarters, QIAGEN regularly offers "health days" where all employees are invited to receive free counsel and to participate in screening and nutrition programs, medical check-ups, etc. QIAGEN provides in-house gyms open to all employees, sports courses coached by professional trainers, and on-site soccer fields and beach volleyball courts, all free of charge. All female employees have free access to screening for HPV, the primary cause of cervical cancer.

## **Future Perspectives**

QIAGEN is playing a pivotal role in the molecular biology revolution by empowering customers to transform raw biological samples into valuable molecular information. We believe QIAGEN is in a strong position to take advantage of the significant opportunities thanks to our global leadership in Sample & Assay Technologies, which is underpinned by a stable and growing customer base, an excellent product portfolio, and a pipeline of innovative projects.

QIAGEN believes the relevant global market for molecular diagnostics and life science research products totals approximately \$70 billion. Among the fundamental growth drivers in the current business environment are ongoing breakthroughs and insights into molecular biology, new technologies to analyze molecular information, improvements in the quality and reductions in cost of healthcare using diagnostics, increasing demands for quality, and revenue streams made possible through consumable products.

We have grown substantially in recent years with a flexible strategy that includes developing innovative new products, partnering, and acquiring companies or technologies to complement our portfolio.

QIAGEN will continue to leverage its global leadership in Sample & Assay Technologies to expand in all customer groups. Our strategies for the future are guided by the QIAGEN vision of making improvements in life possible through the use of our innovative products in a growing number of applications.

### **QIAGEN Perspectives for 2013**

QIAGEN delivered on its goal of accelerating growth and innovation during 2012 by executing on its strategic initiatives despite challenging macroeconomic conditions. We intend to build on this momentum in 2013, leveraging QIAGEN's global leadership in Sample & Assay Technologies by (1) accelerating organic and strategic growth through expansion of the existing portfolio and targeted M&A activity; (2) delivering efficiency and effectiveness by optimizing resource allocation; (3) strengthening QIAGEN's position as employer of choice with best talent and top teams; and (4) enhancing customer experience to exceed the expectations of our 500,000 global customers.

QIAsymphony RGQ, the breakthrough modular platform for sample-to-result laboratory automation, has started a new era of workflow consolidation. This flagship instrument is expected to be a key growth driver during the next decade and sup-

port global expansion in all customer classes, particularly Molecular Diagnostics. QIAGEN exceeded its year-end 2012 goal of more than 750 QIAasympathy systems installed worldwide, and has set a new goal to reach more than 1,000 installed systems through 2013. Customer demand remains strong for QIAasympathy given its many features, including its status as the industry's first automation system that can process both commercial assays and a broad array of laboratory-developed tests from sample to clinical result.

In late 2012 QIAGEN began to roll out new products as part of its initiative to create integrated next-generation sequencing (NGS) workflows designed to enable the routine use of NGS in clinical research and diagnostics. By early 2013, QIAGEN has launched 15 NGS consumable products, all "universal" or compatible with any NGS platform, to enhance pre-analytical sample preparation, DNA library preparation and detection of targeted cancer genes. The platform strategy includes a breakthrough next-generation benchtop sequencer, now in an advanced stage of development, as well as new bioinformatics aimed at accelerating NGS analysis time. QIAGEN's ambition for the future is to make next-generation sequencing, now limited mostly to life science research, a routine and cost-effective tool used in clinical research and healthcare. QIAGEN plans to begin placing its NGS workflows with selected customer groups during 2013.

Meanwhile, QIAGEN is adding high-value content for use on its automated systems, particularly novel biomarkers and companion diagnostics for use in Personalized Healthcare as well as by customers in Pharma and Academia. Among the highlights affecting 2013:

- U.S. market conversion to QIAGEN's *therascreen KRAS RGQ* PCR Kit, approved by the FDA in July 2012 as a companion diagnostic for Erbitux (cetuximab) in patients with metastatic colorectal cancer, is progressing well. The test runs on the Rotor-Gene Q MDx, a key module of the QIAasympathy family.
- In late 2012 QIAGEN submitted the *therascreen EGFR RGQ* PCR Kit to the FDA as a proposed companion diagnostic to guide treatment with afatinib, an investigational compound for certain types of lung cancer that was granted priority review status in January 2013. This test also runs on the Rotor-Gene Q MDx instrument.

- Also in 2012 QIAGEN submitted its "pre-molecular" QuantifErON-CMV test to the FDA, proposed for use in detecting latent infection with cytomegalovirus (CMV), a pathogen which can cause serious illness in immunosuppressed patients, including organ and bone marrow transplant recipients.

- In 2013 QIAGEN is launching its *careHPV* Test and instrument platform in China following 2012 approval by the country's State Food and Drug Administration (SFDA). The *careHPV* Test is the first molecular diagnostic for human papillomavirus that is designed for low-resource clinical settings, such as areas lacking electricity, water or laboratory infrastructure.

- QIAGEN is working to accelerate market adoption of AmniSure, a Point of Need assay for determining whether a pregnant woman is suffering premature rupture of fetal membranes (PROM), a widespread cause of premature delivery and neonatal complications. AmniSure, approved in the U.S. and other markets, was acquired in May 2012 and has now been integrated into QIAGEN's commercial operations.

QIAGEN continues to expand its geographic presence after establishing subsidiaries in Poland in 2012 and beginning direct sales in India and Taiwan during 2011. The top seven emerging markets (Brazil, Russia, India, China, South Korea, Mexico and Turkey) represented more than 10% of net sales in 2012 and generated more than 20% CER growth compared to 2011 when excluding a major product tender in one country in 2011. Ongoing strong growth in these markets is expected in 2013.

To grow more efficiently and effectively, QIAGEN implemented a number of operational improvements during 2012 to enhance productivity and free up resources for growth initiatives. Through creation of the Molecular Diagnostics and Life Sciences business areas in 2012, as well as the integration of regional marketing activities with sales teams, decision-making has been moved closer to customers. Integration of R&D activities into the two business areas has focused innovation on high-growth markets. Actions are also under way to optimize capacity utilization at selected sites and capture savings from shared service functions and outsourcing. QIAGEN expects to implement further projects during 2013 with the aim of improving efficiency and effectiveness. In addition, QIAGEN has initiated changes in its corporate culture to promote focus, accountability and entrepreneurial decision-making.

For 2013, total net sales are expected to rise on a mix of organic growth and contributions from the acquisition of AmniSure in May 2012. Stable cash flows and a strong balance sheet will enable QIAGEN to build its business through internal investments in new products and geographic expansion as well as through targeted acquisitions.

### **Global Economic Perspectives for 2013**

The near-term outlook for the global economy in 2013 is modest growth with regional variations. In the United States gradual expansion continues, supported by a positive financial market, signs of a turnaround in housing, and strengthening consumer sector; however, uncertainties over fiscal policy continue following the "sequestration" of federal spending in early 2013. The Euro area economy remains weak, with particularly high unemployment in southern Europe, although EU-wide policies to contain the sovereign debt crisis have improved financial conditions. Japan's economy is expected to expand modestly under the influence of stimulative policy measures. Emerging-market economies are expected to accelerate in 2013, but not to grow at rates as high as those seen in recent years.

### **Industry Perspectives for 2013**

QIAGEN's customer classes present opportunities, and also uncertainties, for 2013 and beyond. In Molecular Diagnostics, demand continues to grow in 2013 based on the superiority of molecular testing in identifying and profiling many diseases. Companion diagnostics, using genetic biomarkers to personalize care by predicting the usefulness of treatments, are disseminating rapidly with regulatory approvals of new companion diagnostics. On the other hand, pressure to control costs in healthcare is intensifying because of fiscal austerity efforts and the demands of aging populations. The need to create reimbursement policies for Personalized Healthcare, a new area of medicine, poses uncertainty for companion diagnostics. The U.S. healthcare reform law imposed a 2.3% surtax on medical devices (including assays and instruments) starting in 2013, although political uncertainty remains about implementation of reforms that are intended to expand the number of U.S. residents with health benefits starting in 2014. In Applied Testing, the continued expansion of content menus together with dissemination of our platforms will create ongoing opportunities in 2013. Research in Academia will likely face budget restrictions in 2013 from economic weakness and government austerity initiatives in areas of Europe as well as the United States and other markets. The Pharma industry remains in a challenging business environment, although the industry's need to improve effectiveness in devel-

oping new drugs is stronger than ever and supportive of demand for our products. Genomic information and new technologies such as next-generation sequencing continue to transform both the practice of medicine and the process of discovering and commercializing new drugs. QIAGEN intends to pursue growth opportunities across all of its customer classes.

### **Subsequent Events**

Since December 31, 2012, and through February 22, 2013, we repurchased 1.9 million shares under the share repurchase program for approximately \$38.5 million in total.

There were no other events requiring disclosure.



# Corporate Governance Report

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# CORPORATE GOVERNANCE REPORT

QIAGEN recognizes the importance of clear and straightforward rules on corporate governance and, where appropriate, has adapted its internal organization and processes to these rules.

This section provides an overview of QIAGEN's corporate governance structure and includes details of the information required under the Dutch Corporate Governance Code (the "Code"). The Code is applicable to QIAGEN N.V. (in the following also referred to as the "Company"), as it is a publicly listed company incorporated under the laws of the Netherlands with a registered seat in Venlo, the Netherlands. The Code contains the principles and concrete provisions which the persons involved in a listed company (including Managing Board members and Supervisory Board members) and stakeholders should observe in relation to one another.

## Corporate Structure

QIAGEN is a public company with limited liability (naamloze vennootschap) incorporated under Dutch law similar to a "Corporation" (Inc.) in the United States. QIAGEN has a two-tiered board structure. QIAGEN is managed by a Managing Board, which is supervised and advised by a Supervisory Board. It is in the interest of QIAGEN and all its stakeholders that each Board performs its functions appropriately and that there is a clear division of responsibilities between the Managing Board, the Supervisory Board, the general meeting of shareholders ("General Meeting") and the external auditor in a well-functioning system of checks and balances.

## Managing Board

### General

The Managing Board is responsible for the management and the general affairs of QIAGEN as well as defining and achieving QIAGEN's aims, strategy, policies and results. The Managing Board is also responsible for complying with all relevant legislation and regulations as well as for managing the risks associated with the business activities and the financing of QIAGEN. It reports related developments to and discusses the internal risk management and control systems with the Supervisory Board and the Audit Committee. The Ma-

naging Board is accountable for the performance of its duties to the Supervisory Board and the General Meeting. The Managing Board provides the Supervisory Board with timely information necessary for the exercise of the duties of the Supervisory Board. In discharging its duties, the Managing Board takes into account the interests of QIAGEN, its enterprises and all parties involved in QIAGEN, including shareholders and other stakeholders.

### Composition and appointment

QIAGEN has also established an Executive Committee, of which four members served as Managing Directors of QIAGEN in 2012.

Our Managing Board consists of the following individuals:

Name	Age*
<b>Peer M. Schatz</b> Managing Director, Chief Executive Officer	47
<b>Roland Sackers</b> Managing Director, Chief Financial Officer	44
<b>Dr. Joachim Schorr<sup>1</sup></b> Managing Director, Senior Vice President, Research and Development	52
<b>Bernd Uder<sup>2</sup></b> Managing Director, Senior Vice President, Global Sales and Service Solutions	55

\* As of December 31, 2012.

<sup>1</sup> Dr. Joachim Schorr was a member of our Managing Board until April 30, 2012.

<sup>2</sup> Bernd Uder was a member of our Managing Board until December 31, 2012.

The Managing Board consists of one or more members as determined by the Supervisory Board. The members of the Managing Board are appointed by the General Meeting upon the joint meeting of the Supervisory Board and the Managing Board (the "Joint Meeting") having made a binding nomination for each vacancy. However, the General Meeting may at all times overrule the binding nature of such a nomination by a resolution adopted by at least a two-thirds majority of the votes cast, if such majority represents more than half the issued share capital. Managing Directors are

appointed annually for the period beginning on the date following the Annual General Meeting up to and including the date of the Annual General Meeting held in the following year.

Members of the Managing Board may be suspended and dismissed by the General Meeting by a resolution adopted by a two-thirds majority of the votes cast, if such majority represents more than half of the issued share capital, unless the proposal was made by the Joint Meeting, in which case a simple majority of votes cast is sufficient. Furthermore, the Supervisory Board may at any time suspend (but not dismiss) a member of the Managing Board.

### Conflicts of interest

Resolutions to enter into transactions under which members of the Managing Board could have a conflict of interest with QIAGEN, and which are of material significance to QIAGEN and/or the relevant member of the Managing Board, require the approval of the Supervisory Board. QIAGEN has not entered into any such transactions in 2012.

### Remuneration

The remuneration granted to the members of the Managing Board in 2012 consisted of a fixed salary and other variable components, with the significant majority of remuneration awarded in the form of QIAGEN equity.

Variable compensation included annual payments linked to business performance (bonuses), as well as long-term equity incentives that were awarded based on individual performance. Stock options granted to the Managing Board members must have an exercise price that is higher than the market price at the time of grant. Restricted Stock Units granted to the Managing Board members, vest over a 10-year period. Some of these grants contain vesting hurdles related to the achievement of specific operational and financial goals that are not disclosed due to confidential reasons. The long-term vesting periods are designed to strengthen the Managing Board members' commitment to QIAGEN and achieving its strategic initiatives, which in turn would benefit shareholders and other stakeholders.

The tables below state the amounts earned on an accrual basis by our Managing Board members in 2012.

Year ended December 31, 2012		Annual Compensation (\$)		
Name	Fixed Salary	Variable Cash Bonus	Other <sup>3</sup>	Total
<b>Managing Board:</b>				
Peer M. Schatz	1,226,000	168,000	5,000	1,399,000
Roland Sackers	540,000	60,000	34,000	634,000
Dr. Joachim Schorr <sup>1</sup>	113,000	—	635,000	748,000
Bernd Uder <sup>2</sup>	344,000	85,000	20,000	449,000

<sup>1</sup> Dr. Joachim Schorr was a member of our Managing Board until April 30, 2012.

<sup>2</sup> Bernd Uder was a member of our Managing Board until December 31, 2012.

<sup>3</sup> Amounts include, among others, separation payments, inventor bonus and relocation costs. We also occasionally reimburse our Managing Directors' personal expenses related to attending out-of-town meetings but not directly related to their attendance. The value of such reimbursed personal expenses is reported above as "other." Amounts do not include the reimbursement of certain expenses relating to travel incurred at the request of QIAGEN, other reimbursements or payments that in total did not exceed \$10,000 or tax amounts paid by the Company to tax authorities in order to avoid double-taxation under multi-tax jurisdiction employment agreements.

Year ended December 31, 2012		Long-Term Compensation		
Name	Defined Contribution Benefit Plan	Stock Options	Restricted Stock Units	Perfor- mance Stock Units
<b>Managing Board:</b>				
Peer M. Schatz	\$ 84,000	134,109	465,181	50,540
Roland Sackers	\$ 86,000	44,945	155,901	17,213
Dr. Joachim Schorr <sup>1</sup>	\$ 10,000	—	—	—
Bernd Uder <sup>2</sup>	\$ 52,000	19,549	45,207	66,384

<sup>1</sup> Dr. Joachim Schorr was a member of our Managing Board until April 30, 2012.

<sup>2</sup> Bernd Uder was a member of our Managing Board until December 31, 2012.

Further details on the composition of remuneration for the Managing Board, and the implementation of the Remuneration Policy during 2012, are disclosed in the Remuneration Report of the Compensation Committee as published on our website at [www.qiagen.com](http://www.qiagen.com).

## Supervisory Board

### General

The Supervisory Board supervises the policies of the Managing Board, the general course of QIAGEN's affairs and strategy and the business enterprises we operate. The Supervisory Board assists the Managing Board by providing advice relating to the business activities of QIAGEN. In 2012, the Supervisory Board had seven regular meetings that were held with the attendance of the Managing Board, while certain agenda items were discussed exclusively between the Supervisory Board members. In discharging its duties, the Supervisory Board takes into account the interests of QIAGEN, its enterprise and all parties involved in QIAGEN, including shareholders as well as other stakeholders. The Supervisory Board is responsible for the quality of its own performance. In this respect, the Supervisory Board conducts a self-evaluation on an annual basis.

### Composition and appointment

The Supervisory Board consists of at least three members, or a larger number as determined by the Joint Meeting. Members of the Supervisory Board are appointed by the General Meeting upon the Joint Meeting having made a binding nomination for each vacancy. However, the General Meeting may at all times overrule the binding nature of such a nomination by a resolution adopted by at least a two-thirds majority of the votes cast, if such majority represents more than half the issued share capital.

The Supervisory Board shall be composed in a way that enables it to carry out its duties properly and enables its members to act critically and independently of one another and of the Managing Board and any particular interests. To that effect, the Supervisory Board has adopted a profile of its size and composition that takes into account the nature of our business, our activities and the desired expertise and background of the members of the Supervisory Board. The current profile of the Supervisory Board can be found on our website. The Supervisory Board has appointed a chairman who has the duties assigned to him by the Articles of Association and the Code.

Members of the Supervisory Board are appointed for one-year terms for the period beginning on the day after the Annual General Meeting up to and including the day of the Annual General Meeting held in the following year. Members of the Supervisory Board may be suspended and dismissed by the General Meeting by a resolution adopted by a two-

thirds majority of the votes cast, if such majority represents more than half of the issued share capital, unless the proposal was made by the Joint Meeting, in which case a simple majority of votes cast is sufficient.

Name	Age*
<b>Prof. Dr. Detlev H. Riesner</b> Chairman of the Supervisory Board, Supervisory Director and Chairman of the Selection and Appointment Committee	71
<b>Dr. Werner Brandt</b> Supervisory Director and Chairman of the Audit Committee	59
<b>Dr. Metin Colpan</b> Supervisory Director	57
<b>Erik Hornnaess</b> Deputy Chairman of the Supervisory Board, Supervisory Director, Chairman of the Compensation Committee, Member of the Audit Committee and Member of the Selection and Appointment Committee	75
<b>Prof. Dr. Manfred Karobath</b> Supervisory Director and Member of the Compensation Committee	71
<b>Heino von Prondzynski</b> Supervisory Director	63
<b>Elizabeth E. Tallett</b> Supervisory Director and Member of the Audit Committee and Member of the Compensation Committee	63

\* As of December 31, 2012.

The following is a brief summary of the background of each of the Supervisory Directors. References to "QIAGEN" in relation to periods prior to April 29, 1996, refer to QIAGEN GmbH and its consolidated subsidiaries:

**Professor Dr. Detlev H. Riesner**, 71, is a co-founder of QIAGEN. He has been a member of the Supervisory Board since 1996 and was appointed Chairman of the Supervisory Board in 1999, and in 2005, he was also appointed Chairman of the Selection and Appointment Committee. Professor Riesner has held the Chair of Biophysics at the Heinrich Heine University in Düsseldorf since 1980 and retired in 2006. He has held the position of Dean of the Science Faculty (1991-92), Vice President of the University (Research) (1996-99) and Director of Technology (1999-2006). In 2007, he became a member of the University's board of trustees. Prior to that, he was Professor of Biophysical Chemistry at the Darmstadt Institute of Technology and, from 1975 to 1977, Lecturer of Biophysical Chemistry at Hannover Medical School. He has held guest professorships at the Institute of Microbiology, Academia Sinica, Beijing, and the Department of Neurology

at the University of California, San Francisco. He received his M.S. in Physics from Hannover Institute of Technology and his Ph.D. from the University of Braunschweig, with post-graduate work at Princeton University. Professor Riesner is either a member of the Supervisory Board or a director of AC Immune S.A., Lausanne, Evocatal GmbH, Düsseldorf, DRK Blutspendedienst West gGmbH, Hagen, and DIWA GmbH, Düsseldorf. His memberships in the advisory boards of NewLab Bioquality AG and Direvo AG ended in 2006 and SCT GmbH ended in 2011, when the companies were sold. Professor Riesner is also a member of the scientific advisory board of Alberta Prion Research Institute, Canada.

**Dr. Werner Brandt**, 59, joined the Supervisory Board in 2007. In the same year, he was appointed Chairman of the Audit Committee. Dr. Brandt has been a member of the Executive Board and the Chief Financial Officer of SAP AG since 2001. From 1999 to 2001, he was a member of the Executive Board and Chief Financial Officer of the German-American healthcare company, Fresenius Medical Care AG, where he also served as Labor Relations Director. From 1992 to 1999, Dr. Brandt was a member of the Managing Board of Baxter Deutschland GmbH and Vice President for European Operations. In this capacity, he was responsible for Baxter's financial operations in Europe. Dr. Brandt began his career in 1981 at the former Price Waterhouse GmbH (now PricewaterhouseCoopers) in Frankfurt. Dr. Brandt completed his Doctorate in business administration at the Technical University of Darmstadt, Germany, in 1991, after studying business administration at the University of Nuremberg-Erlangen, Germany, from 1976 to 1981. Dr. Brandt is currently a member of the Supervisory Board of Deutsche Lufthansa AG.

**Dr. Metin Colpan**, 57, is a co-founder of QIAGEN and was Chief Executive Officer and a Managing Director from 1985 through 2003. Dr. Colpan has been a member of the Supervisory Board since 2004. Dr. Colpan obtained his Ph.D. and M.S. in Organic Chemistry and Chemical Engineering from the Darmstadt Institute of Technology in 1983. Prior to founding QIAGEN, Dr. Colpan was an Assistant Investigator at the Institute for Biophysics at the University of Düsseldorf. Dr. Colpan has had wide experience in separation techniques, and in the separation and purification of nucleic acids in particular, and has filed many patents in the field. Dr. Colpan currently serves as a Supervisory Board member of Morphosys AG, Munich, Germany, and Qalovis Farmer Automatic Energy GmbH, Laer, Germany. Dr. Colpan previously served as Supervisory Board member of Ingenium Pharmaceuticals AG, GenPat77 Pharmacogenetics AG and GPC Biotech AG, each in Munich, Germany.

**Erik Hornnaess**, 75, has been a member of the Supervisory Board since 1998. He joined the Audit Committee in 2002, the Compensation Committee in 2005 and the Selection and Appointment Committee in 2007. He was appointed Deputy Chairman of the Supervisory Board in 2007. Mr. Hornnaess worked for Astra Pharmaceuticals, Sweden, from 1965 until 1979 in various management positions in Sweden, Australia, and Canada and, for the last three years of this period, as the General Manager for the Benelux region (Belgium, The Netherlands and Luxembourg). In 1979, he joined Abbott Laboratories European Headquarters in Paris, France, and from 1982, he was the Area Vice-President of Abbott Diagnostic Division in Europe, Middle-East and Africa, with headquarters in Wiesbaden, Germany. Mr. Hornnaess retired from Abbott Laboratories on March 1, 1997. Additionally, Mr. Hornnaess served as the Vice-President of European Diagnostic Manufacturers Association (EDMA), Brussels, in the period 1995 through 1997. Mr. Hornnaess graduated from Aarhus Handelshøjskole, Denmark, with an MBA and obtained a P.M.D. from the Harvard Business School.

**Professor Dr. Manfred Karobath**, 71, has been a member of the Supervisory Board since 2000 and joined the Compensation Committee in 2005. Prof. Dr. Karobath studied medicine, and from 1967 to 1980, he worked first in the Dept. of Biochemistry of the University of Vienna and, after a stage as postdoctoral fellow, he joined the Dept. of Psychiatry where he became Professor of Biological Psychiatry. In 1980, he joined Sandoz Pharma in Basel, first, in drug discovery, and later, he became Senior Vice President and head of R&D. In 1992, Prof. Dr. Karobath joined Rhone Poulenc Rorer ("RPR") as President of R&D and Executive Vice President, and later, he became a member of the boards of directors of RPR, Pasteur Mérieux Connought, Centeon and Rhone Poulenc Pharma. He has received several scientific awards and has published 92 scientific papers.

**Heino von Prondzynski**, 63, joined the Supervisory Board as well as the Audit Committee in 2007. Mr. von Prondzynski retired in 2005 from Roche where he served as Chief Executive Officer of Roche Diagnostics and a member of the Executive Committee of the Roche Group. Prior to joining Roche in 2000, Mr. von Prondzynski worked at Chiron, first as General Manager and Chief Executive Officer in Germany and Italy, later as President of the Vaccines Division in Emeryville, USA. Mr. von Prondzynski started his career with Bayer in Germany as a sales representative and later worked in Austria and Brazil as General Manager. He studied mathematics, geography and history at Westfälische Wilhelms University of Münster in Germany. Mr. von Prondzynski

is a director of Koninklijke Philips Electronics NV, Hospira, Inc., HTL Strefa and Epigenomics AG. Mr. von Prondzynski was previously Chairman of Nobel Biocare Holding AG.

**Elizabeth E. Tallett**, 63, joined the Supervisory Board as well as the Audit Committee and Compensation Committee in 2011. Ms. Tallett has been a Principal of Hunter Partners, LLC, a management company for early to mid-stage pharmaceutical, biotechnology and medical device companies, since 2002. Her senior management experience includes President and CEO of Transcell Technologies Inc., President of Centocor Pharmaceuticals, member of the Parke-Davis Executive Committee, and Director of Worldwide Strategic Planning for Warner-Lambert Company. Ms. Tallett graduated from Nottingham University, England, with dual Bachelor's degrees with honors in mathematics and economics. She is a member of the board of directors of Principal Financial Group, Inc., Coventry Health Care, Inc. and Meredith Corp. Ms. Tallett is currently the Lead Director for both Principal and Coventry Health Care. She was also a director of Varian, Inc., Immunicon, Inc., Varian Semiconductor Equipment Associates, Inc. and IntegraMed America, Inc. at times during the past five years. Ms. Tallett was a founding board member of the Biotechnology Council of New Jersey and is a Trustee of Solebury School in Pennsylvania.

### Conflicts of Interest

Resolutions to enter into transactions under which members of the Supervisory Board could have a conflict of interest with QIAGEN, and which are of material significance to QIAGEN and/or the relevant member of the Supervisory Board, require the approval of the Supervisory Board plenum. In 2012, neither QIAGEN nor its Supervisory Board members have entered into any such transactions.

### Committees

The Supervisory Board has established an Audit Committee, a Compensation Committee and a Selection and Appointment (Nomination) Committee from among its members and can establish other committees as deemed beneficial. The Supervisory Board has approved charters under which each of the committees operates. These charters are published on our website ([www.qiagen.com](http://www.qiagen.com)).

### Audit Committee

The Audit Committee's primary duties and responsibilities include, among other things, to serve as an independent and objective party to monitor QIAGEN's accounting and financial reporting process and internal risk management, control

and compliance systems. The Audit Committee is also directly responsible for proposing the external auditor to the Supervisory Board, which then proposes the appointment of the external auditor to the General Meeting. Further, the Audit Committee is responsible for the compensation and oversight of QIAGEN's external auditor and for providing an open avenue of communication among the external auditor as well as the Management Board and the Supervisory Board. Our Internal Audit department operates under the direct responsibility of the Audit Committee. The Audit Committee currently consists of three members: Dr. Brandt (Chairman), Ms. Tallett, and Mr. Hornnaess. The Audit Committee members are appointed by the Supervisory Board and serve for a term of one year. The Supervisory Board has designated Dr. Brandt as a "financial expert" as defined in provisions III.3.2 and III.5.7 of the Code.

The Audit Committee met eight times in 2012 and did meet with the external auditor excluding members of the Managing Board in November 2012. Among other things, the Audit Committee discussed the selection of the external auditor to audit the consolidated financial statements and accounting and records of QIAGEN and its subsidiaries, along with the pre-approval of fees for these services. Further, it reviewed QIAGEN's compliance with various laws and policies, including the Code of Conduct; reviewed the risk management system; discussed the performance of the external auditor with management; and discussed on a quarterly basis the scope and results of the reviews and audits with the external auditor. The Audit Committee also discussed financial accounting and reporting principles and policies as well as the adequacy of internal accounting, financial and operating controls and procedures with the external auditor and management. These discussions included a review of developments in accounting standards and their impact on QIAGEN's financial statements. The Audit Committee considered and approved recommendations regarding changes to QIAGEN's accounting policies and processes. In addition, the Audit Committee reviewed with management and the external auditor all quarterly reports prior to their public release as well as quarterly and annual reports prepared under U.S. GAAP (reported on Forms 6-K and 20-F) for filing with the U.S. Securities and Exchange Commission and the annual report prepared under IFRS. The Audit Committee performs a self-evaluation of its activities on an annual basis.

### Compensation Committee

The Compensation Committee's primary duties and responsibilities include, among other things, the preparation of a proposal for the Supervisory Board concerning the Remuneration Policy for the Managing Board to be adopted by the General

Meeting, the preparation of a proposal concerning the individual compensation of Managing Board members to be adopted by the Supervisory Board and the preparation of the Remuneration Report on compensation policies for the Managing Board to be adopted by the Supervisory Board. The Remuneration Report reviews the implementation of the Remuneration Policy in the most recent year and provides an outline of the Remuneration Policy for the future.

The Compensation Committee currently consists of three members: Mr. Hornnaess (Chairman), Ms. Tallett and Prof. Dr. Karobath. Members are appointed by the Supervisory Board and serve for a term of one year. The Compensation Committee met 12 times in 2012. It reviewed, approved and made recommendations on QIAGEN's compensation and benefits policies, practices and procedures to ensure that legal and fiduciary responsibilities of the Supervisory Board and the Managing Board are carried out. Further, the Compensation Committee approved equity-based remuneration systems and their application, including stock rights or stock option grants on a monthly basis.

#### **Selection and Appointment Committee**

The Selection and Appointment (Nomination) Committee is primarily responsible for the preparation of selection criteria and appointment procedures for members of the Supervisory Board and Managing Board as well as the periodic evaluation of the scope and composition of the Managing Board and the Supervisory Board, including the profile of the Supervisory Board.

Additionally, the Selection and Appointment Committee periodically evaluates the functioning of individual members of the Managing Board and Supervisory Board, reporting these results to our Supervisory Board. It also proposes the (re-)appointments of members of our Managing Board and Supervisory Board and supervises the policy of our Managing Board in relation to selection and appointment criteria for senior management. The Selection and Appointment Committee prepares and submits to our Supervisory Board an annual report of its deliberations and findings.

Current members of the Selection and Appointment Committee are Prof. Dr. Riesner (Chairman) and Mr. Hornnaess. Members are appointed by the Supervisory Board and serve for a one-year term. The Selection and Appointment Committee formally convened once in 2012.

#### **Remuneration**

The Supervisory Board compensation for 2012 consists of fixed retainer compensation, additional retainer amounts for Chairman and Vice Chairman, and committee membership fees. Annual remuneration of the Supervisory Board members is as follows:

<b>Fee paid to each member of the Supervisory Board</b>	<b>€ 30,000</b>
<hr/>	
<b>Additional compensation payable to members holding the following positions:</b>	
Chairman of the Supervisory Board	€ 20,000
Vice Chairman of the Supervisory Board	€ 5,000
Chairman of the Audit Committee	€ 15,000
Chairman of the Compensation Committee	€ 10,000
Fee payable to each member of the Audit Committee	€ 7,500
Fee payable to each member of the Compensation Committee	€ 5,000

Members of the Supervisory Board also receive € 1,000 for attending the Annual General Meeting and € 1,000 for attending each meeting of the Supervisory Board. Members of the Supervisory Board receive € 1,000 for attending each meeting of any subcommittees (other than the Audit Committee, Compensation Committee and Selection and Appointment Committee).

Supervisory Board members also receive variable compensation, which is determined annually by the Compensation Committee pursuant to a formula based on growth of Adjusted Earnings per Share provided that such remuneration will not exceed € 5,000 per year. We did not pay any agency or advisory service fees to members of the Supervisory Board.

(\$)	Fixed Remuneration	Chairman / Vice Chairman Committee	Committee Membership	Meeting Attendance	Subcommittee Meeting Attendance	Variable Cash Remuneration	Total
<b>Name</b>							
<b>Supervisory Board:</b>							
Prof. Dr. Detlev H. Riesner	38,500	25,750	–	6,500	3,750	6,500	81,000
Dr. Werner Brandt	38,500	19,250	–	6,500	–	6,500	70,750
Dr. Metin Colpan	38,500	–	–	6,500	3,750	6,500	55,250
Erik Hornnaess	38,500	19,250	9,500	6,500	–	6,500	80,250
Prof. Dr. Manfred Karobath	38,500	–	6,500	6,500	2,500	6,500	60,500
Heino von Prondzynski	38,500	–	–	5,000	2,500	6,500	52,500
Elizabeth E. Tallett	38,500	–	16,000	5,000	–	6,500	66,000

Supervisory board members also receive a variable component, in the form of share-based compensation. Stock options granted to the Supervisory Board members must have an exercise price that is higher than the market price at the time of grant. During 2012, the following options or other share-based compensation were granted to the members of the Supervisory Board.

Year ended December 31, 2012	Grants	
Name	Stock Options	Restricted Stock Units
<b>Supervisory Board:</b>		
Prof. Dr. Detlev H. Riesner	1,563	10,000
Dr. Werner Brandt	1,563	10,000
Dr. Metin Colpan	1,563	10,000
Erik Hornnaess	1,563	10,000
Prof. Dr. Manfred Karobath	1,563	10,000
Heino von Prondzynski	1,563	10,000
Elizabeth E. Tallett	1,563	10,000

## Share Ownership

The following table sets forth certain information as of January 27, 2013 concerning the ownership of common shares by our directors and officers. In preparing the following table, we have relied on information furnished by such persons.

Name and country of residence	Shares Beneficially Owned <sup>1</sup> Number	Percent Ownership <sup>2</sup>
Peer M. Schatz, Germany	1,771,128 <sup>3</sup>	0.75%
Roland Sackers, Germany	– <sup>4</sup>	*
Bernd Uder, Germany	– <sup>5</sup>	*
Prof. Dr. Detlev H. Riesner, Germany	1,654,993 <sup>6</sup>	0.70%
Dr. Werner Brandt, Germany	8,377 <sup>7</sup>	*
Dr. Metin Colpan, Germany	4,540,961 <sup>8</sup>	1.92%
Erik Hornnaess, Spain	14,180 <sup>9</sup>	*
Prof. Dr. Manfred Karobath, Austria	9,015 <sup>10</sup>	*
Heino von Prondzynski, Switzerland	2,377 <sup>11</sup>	*
Elizabeth E. Tallett, United States	– <sup>12</sup>	*

\* Indicates that the person beneficially owns less than 0.5% of the Common Shares issued and outstanding as of January 27, 2013.

<sup>1</sup> The number of Common Shares issued and outstanding as of January 27, 2013 was 236,563,920. The persons and entities named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them and have the same voting rights as shareholders with respect to Common Shares.

<sup>2</sup> Does not include Common Shares subject to options or awards held by such persons at January 27, 2013. See footnotes below for information regarding options now exercisable or that could become exercisable within 60 days of the date of this table.

- <sup>3</sup> Does not include 2,097,769 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$6.020 to \$22.430 per share. Options expire in increments during the period between 4/2013 and 2/2022. Does not include 265,127 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>4</sup> Does not include 140,137 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$15.590 to \$22.430 per share. Options expire in increments during the period between 2/2018 and 2/2022. Does not include 84,664 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>5</sup> Does not include 77,267 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$15.590 to \$22.430 per share. Options expire in increments during the period between 2/2017 and 2/2022. Does not include 40,801 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>6</sup> Does not include 48,341 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$11.985 to \$22.430 per share. Options expire in increments during the period between 4/2014 and 2/2022. Includes 1,652,068 shares held by Riesner Verwaltungs GmbH, of which Professor Riesner is the sole stockholder. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>7</sup> Does not include 6,399 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$15.590 to \$22.430 per share. Options expire in increments during the period between 4/2018 and 2/2022. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>8</sup> Does not include 348,341 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$6.018 to \$22.430 per share. Options expire in increments during the period between 4/2013 and 2/2022. Includes 3,738,703 shares held by CC Verwaltungs GmbH, of which Dr. Colpan is the sole stockholder and 800,000 shares held by Colpan GbR. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>9</sup> Does not include 48,341 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$11.985 to \$22.430 per share. Options expire in increments during the period between 4/2014 and 2/2022. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>10</sup> Does not include 48,341 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$11.985 to \$22.430 per share. Options expire in increments during the period between 4/2014 and 2/2022. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>11</sup> Does not include 6,399 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices ranging from \$15.590 to \$22.430 per share. Options expire in increments during the period between 4/2018 and 2/2022. Does not include 1,770 shares issuable upon the release of unvested stock awards that could become releasable within 60 days from the date of this table.
- <sup>12</sup> Does not include 521 shares issuable upon the exercise of options now exercisable or that could become exercisable within 60 days from the date of this table having exercise prices of \$15.59 per share. Options expire on 2/2022.

The following table sets forth the vested and unvested options and stock awards of our officers and directors as of January 27, 2013:

Name	Total Vested Options	Total Unvested Options	Expiration Dates	Exercise Price	Total Unvested Restricted and Performance Stock Units
Peer M. Schatz	1,975,214	249,512	4/1/2013 to 2/28/2022	\$ 6.02 to \$ 22.43	1,666,950
Roland Sackers	99,363	83,343	2/28/2018 to 2/28/2022	\$ 15.59 to \$ 22.43	547,408
Bernd Uder	62,202	33,649	2/28/2017 to 2/28/2022	\$ 15.59 to \$ 22.43	257,336
Prof. Dr. Detlev H. Riesner	46,818	3,017	4/1/2014 to 2/28/2022	\$ 11.985 to \$ 22.43	24,945
Dr. Werner Brandt	4,876	3,017	4/29/2018 to 2/28/2022	\$ 15.59 to \$ 22.43	24,407
Dr. Metin Colpan	346,818	3,017	4/1/2013 to 2/28/2022	\$ 6.02 to \$ 22.43	24,945
Erik Hornnaess	46,818	3,017	4/1/2014 to 2/28/2022	\$ 11.985 to \$ 22.43	24,945
Prof. Dr. Manfred Karabath	46,818	3,017	4/1/2014 to 2/28/2022	\$ 11.985 to \$ 22.43	24,945
Heino von Prondzynski	4,876	3,017	4/29/2018 to 2/28/2022	\$ 15.59 to \$ 22.43	24,407
Elizabeth E. Tallett	—	1,563	2/28/2022	\$ 15.59	10,000

## Additional Information

### Shareholders

Our shareholders exercise their voting rights through Annual and Extraordinary General Meetings. Resolutions of the General Meeting are adopted by an absolute majority of votes cast, unless a different majority of votes or quorum is required by Dutch law or the Articles of Association. Each common share confers the right to cast one vote.

Furthermore, the Managing Board, or where appropriate, the Supervisory Board, shall provide all shareholders and other parties in the financial markets with equal and simultaneous information about matters that may influence QIAGEN's share price.

QIAGEN is required to convene an Annual General Meeting in the Netherlands no later than six months following the end of each year. The agenda for the Annual General Meeting must contain certain matters as specified in QIAGEN's Articles of Association and under Dutch law, including, among other things, the adoption of QIAGEN's annual financial statements.

Additional Extraordinary General Meetings may be convened at any time by the Managing Board, the Supervisory Board or by one or more shareholders jointly representing at least 40% of QIAGEN's issued share capital. Furthermore, one or more shareholders, who jointly represent at least 10% of QIAGEN's issued share capital may, on their application, be authorized by the district court judge having applications for interim relief, to convene a General Meeting. Shareholders are entitled to propose items for the agenda of the General Meeting provided that they hold at least 1% of the issued share capital or the shares they hold represent a market value of at least € 50 million. Proposals for agenda items for the General Meeting must be submitted at least 60 days prior to the meeting date. The notice convening a General Meeting, accompanied by the agenda, shall be sent no later than 15 days prior to the meeting. QIAGEN informs the General Meeting by means of explanatory notes to the agenda, providing all facts and circumstances relevant to the proposed resolutions.

## The Audit of Financial Reporting

The external auditor is appointed annually by the General Meeting. The Audit Committee recommends to the Supervisory Board the external auditor to be proposed for (re)appointment by the General Meeting. In addition, the Audit Committee evaluates and, where appropriate, recommends the replacement of the external auditor. The external auditor is invited to attend the meeting of the Supervisory Board at which the financial statements shall be approved and is furthermore invited to attend the General Meeting at which the financial statements are adopted and may be questioned by the General Meeting on its statement on the fairness of our annual accounts. At the Annual General Meeting in 2012, Ernst & Young Accountants was appointed as external auditor for the Company for 2012.

## Share-Based Compensation

The QIAGEN N.V. Amended and Restated 2005 Stock Plan (the Plan) was adopted in 2005. The Plan allows for the granting of stock rights and incentive stock options, as well as non-qualified options, stock grants and stock-based awards, generally with terms of up to 10 years, subject to earlier termination in certain situations. Generally, options vest over a three-year period. The vesting and exercisability of certain stock rights will be accelerated in the event of a Change of Control, as defined in the Plan. To date, all option grants have been at the market value on the grant date or at a premium above the closing market price on the grant date. We issue new Common Shares to satisfy option exercises and had approximately 19.8 million Common Shares reserved and available for issuance under this plan at December 31, 2012.

In connection with the 2007 acquisition of Digene Corporation, we assumed three additional equity incentive plans. No new grants will be made under these plans. We had approximately 0.1 million common shares reserved and available for issuance under these plans at December 31, 2012.

## Stock Options

During the years ended December 31, 2012 and 2011, we granted 592,829 and 601,897 stock options, respectively. The following are the weighted-average assumptions used in valuing the stock options granted to employees for the years ended December 31, 2012, 2011 and 2010:

A summary of the status of employee stock options as of December 31, 2012 and changes during the year then ended is presented below:

	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (in thousands)
<b>All employee options</b>				
Outstanding at January 1, 2012	6,527	\$ 13.61		
Granted	593	\$ 16.00		
Exercised	(1,444)	\$ 11.53		
Forfeited	(82)	\$ 18.90		
Expired	(261)	\$ 17.64		
Outstanding at December 31, 2012	5,333	\$ 14.16	4.09	\$ 25,006
Exercisable at December 31, 2012	4,252	\$ 13.18	2.91	\$ 23,664
Vested and expected to vest at December 31, 2012	5,257	\$ 14.12	4.01	\$ 24,886

## Stock Units

Stock units represent rights to receive Common Shares at a future date and include restricted stock units which are subject to time-vesting only and performance stock units which include performance conditions in addition to time-vesting. There is no exercise price and the fair market value at the time of the grant is recognized over the requisite vesting period, generally ten years.

A summary of stock units as of December 31, 2012 and changes during the year are presented below:

	Stock Units (in thousands)	Weighted Average Contractual Term	Aggregate Intrinsic Value (in thousands)
<b>Stock Units</b>			
Outstanding at January 1, 2012	5,651		
Granted	2,574		
Vested	(831)		
Forfeited	(473)		
Outstanding at December 31, 2012	6,921	2.85	125,602
Vested and expected to vest at December 31, 2012	5,732	2.74	104,029

## Risk Management

QIAGEN has identified various risk factors for our business that are reviewed in detail in the 2012 Form 20-F filed with the U.S. Securities and Exchange Commission. There may be current risks that we have not yet fully assessed or that are currently qualified

as minor, but could have a material adverse impact on our performance in the future. The Managing Board has developed and implemented strategies, controls and mitigation measures to identify current and developing risks as part of our risk management system. A variety of functional experts evaluate these business risks, attempting to mitigate and manage these risks.

Identified risks are subdivided into three types:

- A base business risk is specific to us or our industry that threatens our current and existing business;
- A business growth risk is a risk specific to us or our industry that threatens our future business growth; and
- An underlying business risk comprises risks that are not specific to us or our industry but apply to a larger number of public companies.

All identified risks are evaluated based on their likelihood of occurring and their potential impact (estimated in monetary terms) in disrupting our progress in achieving our business objectives. The overall risk management goal is to identify risks that could significantly threaten our success and to allow management on a timely basis the opportunity to successfully mitigate such risks. The results of the risk assessment and any updates are reported to the Audit Committee on a regular basis. Each quarter a detailed risk reporting update is provided to the Audit Committee for specific risks which have been newly identified or have changed since the last assessment. On a semi-annual basis the overall risk inventory is updated for all risks that are categorized as either a base business risk or a risk to business growth. A detail review of all underlying business risks is done every year. At least once a year, the Supervisory Board discusses the corporate strategy and business risks as well as the results of an assessment by the Managing Board and the Audit Committee on the structure and operations of the internal risk management and control systems, including any significant changes.

#### Risk Types

Base Business Risk	<ul style="list-style-type: none"> <li>Identification and monitoring of competitive threats to the business</li> <li>Monitoring complexity of product portfolio</li> <li>Monitoring dependence on key customers for single product groups</li> <li>Dependence on individual production sites or suppliers</li> <li>Evaluating purchasing initiatives, price controls and changes to reimbursements</li> <li>Monitoring of production risks, including contamination prevention, high-quality product assurance</li> <li>Ensuring ability to defend against intellectual property infringements and maintain competitive advantage after expiration</li> </ul>
Business Growth Risk	<ul style="list-style-type: none"> <li>Managing development and success of key R&amp;D projects</li> <li>Managing successful integration of acquisitions to achieve anticipated benefits</li> </ul>
Underlying Business Risk	<ul style="list-style-type: none"> <li>Financial Risks including Economic risk and fluctuations in currency exchange rates</li> <li>Financial Reporting Risk including monitoring multi-jurisdiction tax compliance</li> <li>Evaluating possible asset impairment events</li> <li>Compliance and Legal risks including safety in operations and environmental hazard risks, compliance with various regulatory bodies and pending regulatory product approvals</li> <li>Risks of FCPA or anti-trust concerns arising from a network of subsidiaries and distributors in foreign countries</li> </ul>

In 2008, QIAGEN established a Compliance Committee under the leadership of the Chief Financial Officer in his function as Chief Compliance Officer. The Compliance Committee, which consists of senior executives from Human Resources, Internal Audit, SEC Reporting, Legal and Regulatory, performs a quarterly assessment of the legal and regulatory risks, and initiates any required corrective actions.

With publicly listed shares in the United States, QIAGEN is subject to Sections 302 and 404 of the Sarbanes Oxley Act. QIAGEN enacted internal controls and procedures over its financial reporting in 2012 as described in more detail in item 15 of the 2012 Annual Report on Form 20-F. In a report on its 2012 audit of internal controls over financial reporting, the external auditor Ernst & Young expressed the opinion that QIAGEN has maintained in all material respects effective internal control over financial reporting as of December 31, 2012, under the applied criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), an organization formed by various professional accounting and auditing associations in the U.S.

#### Whistleblower Policy and Code of Conduct

QIAGEN adopted a Whistleblower Policy concerning the reporting of alleged irregularities within QIAGEN of a general, operational or financial nature. Furthermore, a Code of Conduct was adopted that outlines business principles for our

employees and rules of conduct. The Code of Conduct can be found on our website at [www.qiagen.com](http://www.qiagen.com).

### **Anti-Takeover Measures**

In 2004, the Supervisory Board granted an option to the Dutch Foundation Stichting Preferente Aandelen QIAGEN that allows the Foundation to acquire preference shares from QIAGEN if (i) a person has (directly or indirectly) acquired or has expressed a desire to acquire more than 20% of our issued share capital, or (ii) a person holding at least a 10% interest in the share capital has been designated as a hostile person by our Supervisory Board. The option enables the Foundation to acquire preference shares equal to the number of our outstanding common shares at the time of the relevant exercise of the right, less one share. When exercising the option and exercising its voting rights on these shares, the Foundation must act in the interest of QIAGEN and the interests of our stakeholders. No preference shares are currently outstanding.

### **Comply or Explain**

The corporate governance structure and compliance with the Code is the joint responsibility of the Managing Board and the Supervisory Board. They are accountable for this responsibility to the General Meeting. QIAGEN continues to seek ways to improve its corporate governance by measuring itself against international best practice. The Code was last amended on December 10, 2008, and can be found at [www.commissiecorporategovernance.nl](http://www.commissiecorporategovernance.nl).

Non-application of a specific best practice provision is not in itself considered objectionable by the Code and may well be justified because of particular circumstances relevant to a company. In accordance with Dutch law, we disclose in our Annual Report the application of the Code's principles and best practice provisions.

To the extent that we do not apply certain principles and best practice provisions, or do not intend to apply these in the current or the subsequent year, we state the reasons.

QIAGEN takes a positive view of the Code and applies nearly all of the best practice provisions. However, we prefer not to apply some provisions due to the international character of our business as well as the fact – acknowledged by the Commission that drafted the Code – that existing contractual agreements between QIAGEN and individual members of the Managing Board cannot be set aside at will.

The following provides an overview of exceptions that we have identified:

1. *Best practice provision II.1.1 recommends that a management board member is appointed for a maximum period of four years. A member may be reappointed for a term of not more than four years at a time.*

Members of the Managing Board are appointed annually for a one-year period beginning on the day following the General Meeting up to and including the day of the General Meeting held in the following year. The employment agreements with the Managing Directors have an indefinite term, but can be terminated with a three-month notice period by the Managing Director and with a six-month notice period by QIAGEN. These agreements were entered into before the Code became applicable; the terms were not renegotiated since this was not considered to be in the interest of QIAGEN. The members of the Managing Board have additional employment agreements with other QIAGEN affiliates that have notice periods deviating from terms in the employment agreements with QIAGEN N.V. (Mr. Schatz and Mr. Sackers 36 months).

2. *Best practice provision II.2.4 recommends that the number of granted options shall be dependent on the achievement of challenging targets specified beforehand.*

From time to time, members of our Managing Board are granted options to acquire common shares at an exercise price higher than the market price on the grant date (as determined by reference to an organized trading market or association). Our view is that the "challenging target" has been set at the time of granting the options since the holder cannot realize any value from these options unless the price of our common shares has risen above the exercise price.

3. *Best practice provision II.2.5 recommends that shares granted to management board members without financial consideration shall be retained for a period of at least five years or until at least at the end of the employment, if this period is shorter. The number of shares to be granted shall be dependent on the achievement of clearly quantifiable and challenging targets specified beforehand.*

Members of the Managing Board are granted restricted stock units and performance stock units from time to time.

Restricted stock units represent rights to receive common shares at a future date. The number of granted restricted stock units is dependent upon the achievement of pre-defined performance goals. Restricted stock units are structured so that 40% of a grant vests after three years, 50% after five years and the remaining 10% after ten years. Performance stock units have performance conditions in addition to time-vesting.

4. *Best practice provision II.2.8 recommends that the maximum remuneration in the event of dismissal of a management board member may not exceed one year's salary (the "fixed" remuneration component). If the maximum of one year's salary would be manifestly unreasonable for a management board member who is dismissed during his first term of office, such board member shall be eligible for a severance pay not exceeding twice the annual salary.*

As explained in item 1 (best practice provision II.1.1), in addition to their employment agreements with QIAGEN N.V., the Managing Board members have entered into employment agreements with certain QIAGEN affiliates that have notice periods of either 24 months or 36 months. In case of termination of an agreement without serious cause as defined by the applicable law, the respective affiliate would remain obliged to compensate the Managing Board member for the remaining term of the employment agreement. QIAGEN believes that these contractual arrangements are well justified due to the long tenures of the Managing Board members.

5. *Best practice provision II.2.11 recommends that the supervisory board may recover from the management board members any variable remuneration awarded on the basis of incorrect financial or other data.*

The current employment agreements with the Managing Directors, which were entered into before the recent Code changes took effect, do not include so-called "clawback" provisions. In the event of unjustified variable remuneration awards that were based on incorrect financial or other data, the Supervisory Board would make use of its statutory powers.

6. *Best practice provision III.3.5 recommends that a person may be appointed to the supervisory board for a maximum of three 4-year terms.*

Two members – Prof. Riesner and Prof. Karobath – have tenures on the Supervisory Board that are longer than this provision. Prof. Riesner is one of the founders of QIAGEN, and he has been a member of the Supervisory Board of QIAGEN N.V. since its establishment in 1996, while Prof. Karobath has been a Supervisory Member since 2000. Prof. Riesner contributes his profound scientific expertise and excellent connections in the scientific community to the board profile, while Prof. Karobath contributes significant value through his scientific acumen and extensive experience in various management positions in the pharmaceuticals industry. Both board members have unique knowledge about QIAGEN that is considered to be highly valuable. As a result, QIAGEN strongly supports the reappointment of these members beyond the 12-year term provision as recommended by the Code. Mr. Hornnaess, who has served on the Supervisory Board since 1998, has announced his intention not to stand for re-election at the Annual General Meeting of Shareholders in June 2013.

7. *Best practice provision III.7.1 recommends that a supervisory board member may not be granted any shares and/or rights to shares by way of remuneration.*

QIAGEN has granted stock options to the members of the Supervisory Board as a remuneration component since its establishment. Since 2007, Supervisory Board members have also been granted restricted stock units. This practice is in compliance with international business practice in our industry, and we consider the granting of stock options or stock rights as an important incentive to attract individuals with the required skills and expertise to serve on our Supervisory Board.

8. *Best practice provision IV.1.1 recommends that a general meeting of shareholders is empowered to cancel binding nominations of candidates for the management board and supervisory board, and to dismiss members of either board by a simple majority of votes of those in attendance, although the company may require a quorum of at least one third of the voting rights outstanding for such vote to have force. If such quorum is not represented, but a majority of those in attendance votes in favor of the proposal, a second meeting may be convened and its vote will be binding, even without a one-third quorum.*

Our Articles of Association currently state that the General Meeting may at all times overrule a binding nomination by a resolution adopted by at least a two-thirds

majority of the votes cast, if such majority represents more than half of the issued share capital. Although a deviation from provision IV.1.1 of the Code, the Supervisory Board and the Managing Board hold the view that these provisions will enhance the continuity of QIAGEN's management and policies.

### **Declaration of Compliance of QIAGEN N.V. regarding the German Corporate Governance Code**

In QIAGEN's 2001 Annual Report, the Managing Board and the Supervisory Board of QIAGEN N.V. declared their intention to disclose compliance with the German Corporate Governance Code pursuant to §161 of the German Stock Corporation Law (AktG) or state the deviations for a particular period. QIAGEN N.V. is a company organized under the laws of The Netherlands and subject to the laws, rules and regulations of this country. In addition, our shares are listed on the NASDAQ Stock Exchange. As a result, the compliance of QIAGEN with the German Corporate Governance Code is dependent on the code's compatibility with the laws, rules, regulations and customs that QIAGEN is subject to in The Netherlands and the U.S. QIAGEN declares compliance with the German Corporate Governance Code with the following exceptions:

#### **1. Item 3.8 paragraph 2**

*If the company takes out a D&O (directors' and officers' liability insurance) policy for the Management Board, a deductible of at least 10% of the loss up to at least the amount of one and a half times the fixed annual compensation of the Management Board member must be agreed upon.*

*A similar deductible must be agreed upon in any D&O policy for the Supervisory Board.*

*QIAGEN's D&O insurance policy provides for a fixed deductible of \$ 10,000 for members of the Managing Board and the Supervisory Board, which we consider an appropriate sign by our members of taking responsibility for their actions.*

#### **2. Item 4.2.3 paragraph 3**

*For instance, share or index-based compensation elements related to the enterprise may come into consideration as variable components. These elements shall be related to demanding, relevant comparison parameters. Changing such performance targets or the comparison*

*parameters retroactively shall be excluded. For extraordinary developments a possibility of limitation (cap) must in general be agreed upon by the Supervisory Board.*

*From time to time, the members of our Managing Board are granted restricted stock units, performance stock units and options to acquire common shares at an exercise price set 2% higher than the market price on the grant date (as determined by reference to an organized trading market or association). These option rights and stock units are subject to multiyear vesting periods and sales restrictions. Members of the Managing Board cannot realize any profit from these grants unless they succeed in increasing shareholder value on a long-term period. For these reasons, as well as to ensure comparability to equity-based incentives granted by peer companies in our industry, we consider these terms to be the most appropriate comparison parameters for the restricted stock units and stock options granted to Managing Board members. The stock units have performance requirements that must be met in addition to the time-vesting conditions.*

#### **3. Item 4.2.3 paragraph 4 and 5**

*In concluding Management Board contracts, care shall be taken to ensure that payments made to a Management Board member on premature termination of his contract without serious cause do not exceed the value of two years' compensation (severance payment cap) and compensate no more than the remaining term of the contract. The severance payment cap shall be calculated on the basis of the total compensation for the past full financial year and if appropriate also the expected total compensation for the current financial year.*

*Payments promised in the event of premature termination of a Management Board member's contract due to a change of control shall not exceed 150% of the severance payment cap.*

*The employment agreements with Managing Directors have an indefinite term, but can be terminated with a three-month notice period by the Managing Director and with a six-month notice period by QIAGEN. The members of the Managing Board have additional employment agreements with other QIAGEN affiliates that have longer notice periods (Mr. Schatz and Mr. Sackers 36 months). In case of a termination without serious cause as defined by the applicable law, QIAGEN would remain*

*obliged to compensate the Managing Board Member for the remaining term of the agreement.*

*No arrangements exist for early retirement of Managing Board members. In the event of the sale or transfer of all or substantially all of QIAGEN's assets or business to an acquirer in one or several transactions including a merger, consolidation or a transfer of shares to a third party, the Managing Board members are entitled to a Change of Control bonus payment commensurate to a multiple (Mr. Schatz 5 times, Mr. Sackers 3 times) of their annual salary (fixed payment and annual bonus). QIAGEN believes that these severance and Change of Control agreements are appropriate due to the long tenures of the Managing Board members.*



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# FINANCIAL RESULTS

## Consolidated Balance Sheets: Assets

	Note	As of December 31	
\$ 1,000		2012	2011
<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents		394,037	221,133
Short-term investments	(7)	90,451	54,577
Accounts receivable, net of allowance for doubtful accounts of \$ 5,221 and \$ 4,315 in 2012 and 2011, respectively	(3)	250,729	230,770
Income taxes receivable		39,150	19,009
Inventories, net	(3)	135,293	132,236
Prepaid expenses and other current assets	(8)	55,363	59,055
Deferred income taxes	(16)	27,598	28,609
<b>Total current assets</b>		<b>992,621</b>	<b>745,389</b>
<b>Long-term assets:</b>			
Property, plant and equipment, net	(9)	418,932	371,792
Goodwill	(11)	1,759,898	1,733,722
Intangible assets, net of accumulated amortization of \$ 532,006 and \$ 417,430 in 2012 and 2011, respectively	(11)	853,872	819,487
Deferred income taxes	(16)	2,323	3,141
Other long-term assets		59,985	56,154
<b>Total long-term assets</b>		<b>3,095,010</b>	<b>2,984,296</b>
<b>Total assets</b>		<b>4,087,631</b>	<b>3,729,685</b>

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

**Consolidated Balance Sheets: Liabilities and Equity**

	Note	As of December 31	
		2012	2011
<b>\$ 1,000, except par value</b>			
<b>Liabilities and equity</b>			
<b>Current liabilities:</b>			
Current portion of long-term debt	(15)	948	1,617
Short-term loans	(15)	–	142,329
Accounts payable		51,311	59,848
Accrued and other liabilities (of which \$7,008 and \$7,383 in 2012 and 2011 due to related parties)	(12), (23)	196,447	213,769
Income taxes payable		14,863	31,211
Deferred income taxes	(16)	3,300	2,862
<b>Total current liabilities</b>		<b>266,869</b>	<b>451,636</b>
<b>Long-term liabilities:</b>			
Long-term debt, net of current portion (of which \$445,000 in 2012 and 2011 due to related parties)	(15), (23)	846,044	446,005
Deferred income taxes	(16)	191,609	210,365
Other liabilities		58,746	63,881
<b>Total long-term liabilities</b>		<b>1,096,399</b>	<b>720,251</b>
<b>Commitments and contingencies</b>	(20)		
<b>Equity:</b>			
Preference shares, 0.01 EUR par value, authorized – 450,000 shares, no shares issued and outstanding		–	–
Financing preference shares, 0.01 EUR par value, authorized – 40,000 shares, no shares issued and outstanding		–	–
Common shares, 0.01 EUR par value, authorized – 410,000 shares, issued and outstanding – 236,487 and 234,221 shares at December 31, 2012 and 2011, respectively		2,769	2,739
Additional paid-in capital		1,718,163	1,673,733
Retained earnings		985,434	855,928
Accumulated other comprehensive income	(17)	43,991	15,904
Less treasury shares, at cost – 1,943 shares at December 31, 2012	(18)	(35,653)	–
Equity attributable to the owners of QIAGEN N.V.		2,714,704	2,548,304
Noncontrolling interest		9,659	9,494
<b>Total equity</b>		<b>2,724,363</b>	<b>2,557,798</b>
<b>Total liabilities and equity</b>		<b>4,087,631</b>	<b>3,729,685</b>

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

## Consolidated Statements of Income

	Note	2012	2011	2010
<b>\$ 1,000, except per share data</b>				
Net sales	(3)	1,254,456	1,169,747	1,087,431
Cost of sales		430,432	419,938	371,869
Gross profit		824,024	749,809	715,562
 <b>Operating expenses:</b>				
Research and development	(3)	122,476	130,636	126,040
Sales and marketing		343,549	307,332	267,484
General and administrative, restructuring integration and other	(3), (6)	152,068	185,507	110,009
Acquisition-related intangible amortization		36,117	26,746	23,492
Total operating expenses		654,210	650,221	527,025
Income from operations		169,814	99,588	188,537
 <b>Other income (expense):</b>				
Interest income		2,382	6,128	4,457
Interest expense		(23,452)	(25,358)	(27,815)
Other (expense) income, net		(3,591)	15,854	7,942
Total other expense		(24,661)	(3,376)	(15,416)
Income before provision for income taxes		145,153	96,212	173,121
Provision for income taxes	(3), (16)	15,616	1,263	28,810
<b>Net income</b>		<b>129,537</b>	<b>94,949</b>	<b>144,311</b>
 <b>Net income (loss) attributable to noncontrolling interest</b>		31	(1,089)	-
 <b>Net income attributable to the owners of QIAGEN N.V.</b>		<b>129,506</b>	<b>96,038</b>	<b>144,311</b>
 <b>Basic net income per common share attributable to the owners of QIAGEN N.V.</b>		<b>0.55</b>	<b>0.41</b>	<b>0.62</b>
 <b>Diluted net income per common share attributable to the owners of QIAGEN N.V.</b>		<b>0.54</b>	<b>0.40</b>	<b>0.60</b>
 <b>Weighted-average common shares outstanding (in thousands)</b>				
Basic	(19)	235,582	233,850	232,635
Diluted	(19)	240,746	239,064	240,483

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

**Consolidated Statements of Comprehensive Income**

	Note \$ 1,000	Years ended December 31		
		2012	2011	2010
<b>Net income</b>		129,537	94,949	144,311
Gains on cash flow hedges, before tax	(13)	305	5,417	14,636
Reclassification adjustments on cash flow hedges, before tax	(13)	781	(3,961)	(8,874)
Cash flow hedges, before tax		1,086	1,456	5,762
(Losses) gains on pensions, before tax		(863)	180	(184)
Foreign currency translation adjustments, before tax		27,639	(51,383)	10,920
Other comprehensive income (loss), before tax		27,862	(49,747)	16,498
Income tax relating to components of other comprehensive income (loss)		416	(1,174)	(1,890)
Total other comprehensive income (loss), after tax		28,278	(50,921)	14,608
<b>Comprehensive income</b>		157,815	44,028	158,919
Comprehensive (income) loss attributable to noncontrolling interest		(222)	3,160	-
<b>Comprehensive income attributable to the owners of QIAGEN N.V.</b>		<b>157,593</b>	<b>47,188</b>	<b>158,919</b>

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

### Consolidated Statements of Changes in Equity

	Note	Common Shares		Additional Paid-In Capital	Retained Earnings
\$ 1,000 except shares		Shares	Amount		
<b>Balance at December 31, 2009</b>		232,074	2,711	1,622,733	615,579
Net income		—	—	—	144,311
Unrealized gain, net on hedging contracts		—	—	—	—
Realized gain, net on hedging contracts		—	—	—	—
Unrealized loss, net on pension		—	—	—	—
Translation adjustment, net		—	—	—	—
Common stock issuances under employee stock plans		1,041	13	11,228	—
Excess tax benefit of employee stock plans		—	—	445	—
Share-based compensation		—	—	13,592	—
Proceeds from subscription receivables		—	—	987	—
<b>Balance at December 31, 2010</b>		<b>233,115</b>	<b>2,724</b>	<b>1,648,985</b>	<b>759,890</b>
Acquisition of Ipsogen S.A.		—	—	—	—
Acquisition of Ipsogen S.A. shares from noncontrolling interests		—	—	—	—
Net income		—	—	—	96,038
Unrealized gain, net on hedging contracts		—	—	—	—
Realized gain, net on hedging contracts		—	—	—	—
Unrealized gain, net on pension		—	—	—	—
Translation adjustment, net		—	—	—	—
Common stock issuances under employee stock plans		1,106	15	8,763	—
Excess tax benefit of employee stock plans		—	—	(4,565)	—
Share-based compensation		—	—	19,539	—
Proceeds from subscription receivables		—	—	1,011	—
<b>Balance at December 31, 2011</b>		<b>234,221</b>	<b>2,739</b>	<b>1,673,733</b>	<b>855,928</b>
Acquisition of Ipsogen S.A. shares from noncontrolling interests		—	—	—	—
Net income		—	—	—	129,506
Unrealized gain, net on hedging contracts	(17)	—	—	—	—
Realized gain, net on hedging contracts	(17)	—	—	—	—
Unrealized loss, net on pension	(17)	—	—	—	—
Translation adjustment, net	(17)	—	—	—	—
Purchase of treasury shares	(18)	—	—	—	—
Common stock issuances under employees stock plans		2,266	30	16,549	—
Excess tax benefit of employee stock plans		—	—	1,489	—
Share-based compensation	(21)	—	—	25,356	—
Proceeds from subscription receivables		—	—	1,036	—
<b>Balance at December 31, 2012</b>		<b>236,487</b>	<b>2,769</b>	<b>1,718,163</b>	<b>985,434</b>

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

Accumulated Other Comprehensive Income (Loss)	Treasury Shares		Equity Attributable to the Owners of QIAGEN N.V.	Non- controlling Interest	Total Equity
	Shares	Amount			
50,146	—	—	2,291,169	—	2,291,169
—	—	—	144,311	—	144,311
9,807	—	—	9,807	—	9,807
(6,125)	—	—	(6,125)	—	(6,125)
(129)	—	—	(129)	—	(129)
11,055	—	—	11,055	—	11,055
—	—	—	11,241	—	11,241
—	—	—	445	—	445
—	—	—	13,592	—	13,592
—	—	—	987	—	987
64,754	—	—	2,476,353	—	2,476,353
—	—	—	—	42,437	42,437
—	—	—	—	(29,783)	(29,783)
—	—	—	96,038	(1,089)	94,949
3,707	—	—	3,707	—	3,707
(2,825)	—	—	(2,825)	—	(2,825)
126	—	—	126	—	126
(49,858)	—	—	(49,858)	(2,071)	(51,929)
—	—	—	8,778	—	8,778
—	—	—	(4,565)	—	(4,565)
—	—	—	19,539	—	19,539
—	—	—	1,011	—	1,011
15,904	—	—	2,548,304	9,494	2,557,798
—	—	—	—	(57)	(57)
—	—	—	129,506	31	129,537
209	—	—	209	—	209
553	—	—	553	—	553
(598)	—	—	(598)	—	(598)
27,923	—	—	27,923	191	28,114
—	(1,943)	(35,653)	(35,653)	—	(35,653)
—	—	—	16,579	—	16,579
—	—	—	1,489	—	1,489
—	—	—	25,356	—	25,356
—	—	—	1,036	—	1,036
43,991	(1,943)	(35,653)	2,714,704	9,659	2,724,363

## Consolidated Statements of Cash Flows

	Note	2012	2011	2010	Years ended December 31
<b>\$ 1,000</b>					
<b>Cash flows from operating activities:</b>					
Net income		129,537	94,949	144,311	
Adjustments to reconcile net income to net cash provided by operating activities, net of effects of businesses acquired:					
Depreciation and amortization		197,892	167,377	142,779	
Non-cash acquisition, impairment and restructuring related costs		16,909	43,029	-	
Share-based compensation expense	(21)	25,356	19,539	13,592	
Excess tax benefits from share-based compensation		(1,489)	(4,153)	(1,976)	
Deferred income taxes	(16)	(22,767)	(31,861)	(19,942)	
Changes in fair value of contingent consideration	(14)	(11,463)	253	-	
Other		(5,227)	(1,437)	(12,113)	
Net changes in operating assets and liabilities:					
Accounts receivable	(3)	(14,289)	(28,203)	(6,884)	
Inventories	(3)	(20,376)	(15,945)	2,348	
Prepaid expenses and other	(8)	3,456	(10,082)	6,431	
Other assets		7	(4,183)	(2,965)	
Accounts payable		(9,945)	7,261	3,482	
Accrued and other liabilities	(12)	(13,255)	19,577	(26,983)	
Income taxes	(16)	(35,328)	(6,244)	13,639	
Other		5,862	(5,098)	(4,967)	
<b>Net cash provided by operating activities</b>		<b>244,880</b>	<b>244,779</b>	<b>250,752</b>	
<b>Cash flows from investing activities:</b>					
Purchases of property, plant and equipment		(101,996)	(86,805)	(79,666)	
Proceeds from sale of equipment		1,312	2,020	3,474	
Purchases of intangible assets		(26,089)	(34,583)	(44,243)	
Proceeds from sale/cash paid for investments		(8,173)	(19,284)	7,985	
Purchases of short-term investments	(7)	(39,942)	(186,817)	(110,076)	
Sales of short-term investments	(7)	5,999	242,630	44,000	
Cash paid for acquisitions, net of cash acquired	(5)	(131,997)	(457,483)	(36,985)	

**Consolidated Statements of Cash Flows**

	Note	Years ended December 31		
		2012	2011	2010
<b>\$ 1,000</b>				
Net cash used in investing activities		(300,886)	(540,322)	(215,511)
<b>Cash flows from financing activities:</b>				
Net repayment / proceeds from short-term debt	(15)	(143,311)	142,329	-
Proceeds from debt	(15)	400,000	44,000	3,016
Repayment of debt	(15)	(1,607)	(469,857)	(50,000)
Cash paid for debt issuance costs	(15)	(2,084)	-	-
Principal payments on capital leases		(3,780)	(3,703)	(3,262)
Proceeds from subscription receivables		1,036	1,011	987
Excess tax benefits from share-based compensation		1,489	4,153	1,976
Proceeds from the exercise of stock options		16,579	8,778	11,241
Purchase of treasury shares	(18)	(35,653)	-	-
Acquisition of noncontrolling interest		(57)	(29,783)	-
Other financing activities		(6,008)	(7,558)	814
Net cash provided by (used in) financing activities		226,604	(310,630)	(35,228)
Effect of exchange rate changes on cash and cash equivalents		2,306	(1,101)	2,837
Net increase (decrease) in cash and cash equivalents		172,904	(607,274)	2,850
Cash and cash equivalents, beginning of year		221,133	828,407	825,557
<b>Cash and cash equivalents, end of year</b>		<b>394,037</b>	<b>221,133</b>	<b>828,407</b>
<b>Supplemental cash flow disclosures:</b>				
Cash paid for interest		17,298	20,760	25,557
Cash paid for income taxes		61,586	41,494	33,781
<b>Supplemental disclosure of non-cash investing and financing activities:</b>				
Equipment purchased through capital lease		492	545	1,185
Investment acquired in non-monetary exchange		3,842	-	-
Intangible assets acquired in non-monetary exchange		5,658	-	30,341

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

# Notes to Consolidated Financial Statements

**December 31, 2012**

## 1. Corporate Information and Basis of Presentation

QIAGEN N.V. is a public limited liability company ('naamloze vennootschap') under Dutch law with registered office at Spoorstraat 50, Venlo, The Netherlands. QIAGEN N.V., a Netherlands holding company, and subsidiaries (we, our or the Company) is a leading provider of innovative Sample and Assay Technologies. These technologies – consumable products such as sample and assay kits and automated instrumentation systems – empower customers to transform raw biological samples into valuable molecular information. We serve four major customer classes: Molecular Diagnostics laboratories; Applied Testing customers in fields such as forensics, veterinary diagnostics and food safety; Pharmaceutical research and development groups, and Academic researchers. We market our products in more than 100 countries.

The accompanying consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (GAAP) and all amounts are presented in U.S. dollars rounded to the nearest thousand, unless otherwise indicated. The consolidated financial statements have been prepared on a historical cost basis, except for derivative financial instruments, contingent consideration and available-for-sale financial instruments that have been measured at fair value.

On May 3, 2012, we acquired AmniSure International LLC, located in Boston, Massachusetts (AmniSure). Accordingly, as of May 3, 2012, all of the assets acquired and liabilities assumed were recorded at their respective fair values and our consolidated results of operations for the periods ended December 31, 2012 include AmniSure's operating results from May 3, 2012 through December 31, 2012.

## 2. Effects of New Accounting Pronouncements

### **Adoption of New Accounting Standards**

In May 2011, the Financial Accounting Standards Board (FASB) issued ASU No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS, to amend FASB ASC 820, Fair Value Measurement, to improve comparability of fair value measurements in both U.S. GAAP and IFRS financial statements. Under these amendments, the FASB does not intend to cause any change in the application of the requirements under Topic 820. Some amendments provide clarification on the application of existing fair value measurement requirements, while other amendments change a particular principle or requirement for measuring fair value, or change disclosure requirements about fair value measurements. This guidance became effective for us on January 1, 2012, and the adoption had no effect on our financial position, results of operations or cash flows.

In September 2011, the FASB issued ASU No. 2011-08, Intangibles-Goodwill and Other (Topic 350) (ASU 2011-08), permitting entities the option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill

impairment test. ASU No. 2011-08 was effective for the Company January 1, 2012, and the adoption had no effect on our financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income, to increase the prominence of items reported in other comprehensive income and to facilitate convergence of U.S. GAAP and IFRS. This amendment requires that all nonowner changes in equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The amendment therefore eliminates the option to present components of other comprehensive income as part of the statement of changes in equity. This amendment does not change the items reported under other comprehensive income, it does not change when an item of other comprehensive income must be reclassified to net income and entities can choose to show line items net of tax effects or show one amount of aggregate income tax expense or benefit. This amendment must be applied retrospectively and for public entities, these amendments become effective for interim and fiscal periods beginning after December 15, 2011. We comply with the provisions of this amendment by using the two statement approach.

#### **New Accounting Standards Not Yet Adopted**

In December 2011, the FASB issued Accounting Standards Update No. 2011-11, "Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities," (ASU 2011-11). ASU 2011-11 enhances disclosures regarding financial instruments and derivative instruments. Entities are required to provide both net information and gross information for these assets and liabilities in order to enhance comparability between those entities that prepare their financial statements on the basis of U.S. GAAP and those entities that prepare their financial statements on the basis of IFRS. The requirements of ASU 2011-11 are to be applied retrospectively and are effective for us on January 1, 2013. We do not expect the adoption of these provisions to have a material impact on our consolidated financial statements.

In July 2012, the FASB issued ASU No. 2012-02, Intangibles-Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02), allowing entities the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. If the qualitative assessment indicates it is more likely than not that the fair value of an indefinite-lived intangible asset is less than its carrying amount, the quantitative impairment test is required. Otherwise, no testing is required. ASU 2012-02 is effective for us in the period beginning January 1, 2013, and the adoption is not expected to have an effect on our financial position, results of operations or cash flows.

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, "Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income" (ASU 2013-02). Under ASU 2013-02, an entity is required to provide information about the amounts reclassified out of AOCI by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. ASU 2013-02 is effective for us on January 1, 2013.

### **3. Summary of Significant Accounting Policies and Critical Accounting Estimates**

#### **Principles of Consolidation**

The consolidated financial statements include the accounts of QIAGEN N.V. and its wholly-owned subsidiaries that are not considered variable interest entities. All significant intercompany accounts and transactions have been eliminated. Investments in companies where we exercise significant influence over the operations but do not have control, and where we are not the primary beneficiary, are accounted for using the equity method. All other investments are accounted for under the cost method. When there is a portion of equity in an acquired subsidiary not attributable, directly or indirectly, to the Company, we record the fair value of the noncontrolling interests at the acquisition date and classify the amounts attributable to noncontrolling interests separately in equity in the consolidated financial statements. Any subsequent changes in the Company's ownership interest while the Company retains its controlling financial interest in its subsidiary are accounted for as equity transactions.

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingencies at the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### **Concentrations of Risk**

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

The financial instruments used in managing our foreign currency and interest rate exposures have an element of risk in that the counterparties may be unable to meet the terms of the agreements. We attempt to minimize this risk by limiting the counterparties to a diverse group of highly-rated international financial institutions. The carrying values of our financial instruments incorporate the non-performance risk by using market pricing for credit risk. However, we have no reason to believe that any counterparties will default on their obligations and therefore do not expect to record any losses as a result of counterparty default. In order to minimize our exposure with any single counterparty, we have entered into master agreements which allow us to manage the exposure with the respective counterparty on a net basis. In connection with such agreements, we do not require and are not required to pledge collateral for derivative transactions.

Other financial instruments that potentially subject us to concentrations of credit risk are cash and cash equivalents, short-term investments, and accounts receivable. We attempt to minimize the risks related to cash and cash equivalents and short-term investments by dealing with highly-rated financial institutions and investing in a broad and diverse range of financial instruments. We have established guidelines related to credit quality and maturities of investments intended to maintain safety and liquidity. Concentration of credit risk with respect to accounts receivable is limited due to a large and diverse customer base, which is dispersed over different geographic areas. Allowances are maintained for potential credit losses and such losses have historically been within expected ranges.

### **Foreign Currency Translation**

Our reporting currency is the U.S. dollar and our subsidiaries' functional currencies are generally the local currency of the respective countries in which they are headquartered. All amounts in the financial statements of entities whose functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows: (1) assets and liabilities at period-end rates, (2) income statement accounts at average exchange rates for the period, and (3) components of equity at historical rates. Translation gains or losses are recorded in equity, and transaction gains and losses are reflected in net income as a component of other income, net. Realized gains or losses on the value of derivative contracts entered into to hedge the exchange rate exposure of receivables and payables are also included in net income as a component of other income, net. The net gain (loss) on foreign currency transactions in 2012, 2011 and 2010 was \$(7.2) million, \$ 12.4 million, and \$ 2.6 million, respectively, and is included in other (expense) income, net.

### **Segment Information**

We determined that we operate as one operating segment in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 280, Segment Reporting. Our chief operating decision maker (CODM) makes decisions based on the Company as a whole. In addition, we have a common basis of organization and types of products and services which derive revenues and consistent product margins. Accordingly, we operate and make decisions as one reporting unit.

### **Revenue Recognition**

Our revenues are reported net of sales and value added taxes, discounts and sales allowances, and are derived primarily from the sale of consumable and instrumentation products, and to a much lesser extent, from the sale of services, intellectual property and technology. We recognize revenue when four basic criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

**Consumable and Related Products:** Revenue from consumable product sales typically accounts for approximately 83-87% of our net sales and is generally recognized upon transfer of title consistent with the shipping terms. We maintain a small amount, on average less than \$ 3.0 million in total, of consignment inventory at certain customer locations. Revenues for the consumable prod-

ucts which are consigned in this manner are recognized upon consumption. We generally allow returns of consumable products if the product is returned in a timely manner and in good condition. Allowances for returns are provided for based upon the historical pattern of returns and management's evaluation of specific factors that impact the risk of returns.

Revenues from related products include license fees, intellectual property and patent sales, royalties and milestone payments and typically account for approximately 1-3 % of our net sales. License fees from research collaborations include payments for technology transfer and access rights. Non-refundable, up-front payments received in connection with collaborative research and development agreements are generally deferred and recognized on a straight-line basis over the contract period during which there is any continuing obligation. Revenue from intellectual property and patent sales is recognized when earned, either at the time of sale, or over the performance period. Payments for milestones, generally based on the achievement of substantive and at-risk performance criteria, are recognized in full at such time as the specified milestone has been achieved according to the terms of the agreement. Royalties from licensees are based on reported sales of licensed products, and revenues are calculated based on contract terms when reported sales are reliably measurable, fees are fixed or determinable and collectability is reasonably assured.

**Instrumentation:** Revenue from instrumentation includes the instrumentation equipment, installation, training and other instrumentation services, such as extended warranty services or product maintenance contracts, and typically account for approximately 10-15 % of net sales. Revenue from instrumentation equipment is generally recognized when title passes to the customer, upon either shipment or written customer acceptance after satisfying any installation and training requirements.

We offer our customers access to our instrumentation via reagent rental agreements which place instrumentation with customers without requiring them to purchase the equipment. Instead, we recover the cost of providing the instrumentation in the amount charged for Sample and Assay Technology consumable products. The instruments placed with customers under a reagent rental agreement are depreciated and charged to cost of sales on a straight-line basis over the estimated life of the instrument, typically 3 to 5 years. The costs to maintain these instruments in the field are charged to cost of sales as incurred. Revenue from these reagent rental agreements is generally recognized as the consumable products are shipped.

We have contracts with multiple elements which are accounted for under ASC 605-25, Revenue Recognition – Multiple-Element Arrangements. Multiple-element arrangements are assessed to determine whether there is more than one unit of accounting. In order for a deliverable to qualify as a separate unit of accounting, all of the following criteria must be met:

- The delivered items have value to the client on a stand-alone basis;
- The arrangement includes a general right of return relative to the delivered items, and
- Delivery or performance of the undelivered items is considered probable and substantially in the control of the Company.

Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. Effective as of January 1, 2011, when applying the relative selling price method, the selling price for each deliverable is determined using (a) vendor-specific objective evidence of selling price, if it exists; or otherwise (b) third-party evidence of selling price. If neither vendor-specific objective evidence nor third-party evidence of selling price exists for a deliverable, then the best estimated selling price for the deliverable is used. Prior to January 1, 2011, only the vendor-specific objective evidence of selling price was used. The arrangement consideration is allocated to the separate units of accounting based on each unit's relative fair value. Revenue is then recognized using a proportional-performance method, such as recognizing revenue based on relative fair value of products or services delivered, or on a straight-line basis as appropriate. If these criteria are not met, deliverables included in an arrangement are accounted for as a single unit of accounting and revenue and costs are deferred until the period in which the final deliverable is provided.

### **Warranty**

We provide warranties on our products against defects in materials and workmanship generally for a period of one year. A provision for estimated future warranty costs is recorded in cost of sales at the time product revenue is recognized. Product warranty obligations are included in accrued and other liabilities in the accompanying consolidated balance sheets. The changes in the carrying amount of warranty obligations are as follows:

	Total
<b>\$ 1,000</b>	
<b>Balance at December 31, 2010</b>	<b>3,440</b>
Provision charged to cost of sales	4,376
Usage	(3,649)
Adjustments to previously provided warranties, net	(198)
Currency translation	(59)
<b>Balance at December 31, 2011</b>	<b>3,910</b>
Provision charged to cost of sales	4,631
Usage	(4,099)
Adjustments to previously provided warranties, net	(213)
Currency translation	134
<b>Balance at December 31, 2012</b>	<b>4,363</b>

### **Research and Development**

Research and product development costs are expensed as incurred. Research and development expenses consist primarily of salaries and related expenses, facility costs and amounts paid to contract research organizations, and laboratories for the provision of services and materials as well as costs for internal use or clinical trials.

### **Government Grants**

We recognize government grants when there is reasonable assurance that all conditions will be complied with and the grant will be received. Our government grants generally represent subsidies for specified activities and are therefore recognized when earned as a reduction of the expenses recorded for the activity that the grants are intended to compensate. Thus, when the grant relates to research and development expense, the grant is recognized over the same period that the related costs are incurred. Otherwise, amounts received under government grants are recorded as liabilities in the balance sheet. When the grant relates to an asset, the value of the grant is deducted from the carrying amount of the asset and recognized over the same period that the related asset is depreciated.

### **Shipping and Handling Income and Costs**

Shipping and handling costs charged to customers are recorded as revenue in the period that the related product sale revenue is recorded. Associated costs of shipping and handling are included in sales and marketing expenses. For the years ended December 31, 2012, 2011 and 2010, shipping and handling costs totaled \$23.4 million, \$24.0 million and \$19.9 million, respectively.

### **Advertising Costs**

The costs of advertising are expensed as incurred and are included as a component of sales and marketing expense. Advertising costs for the years ended December 31, 2012, 2011 and 2010 were \$6.6 million, \$6.3 million and \$7.6 million, respectively.

### **General and Administrative, Integration and Other**

General and administrative expenses primarily represent the costs required to support administrative infrastructure. In addition, we incur indirect acquisition and business integration costs in connection with business combinations. These costs represent incremental costs that we believe would not have been incurred absent the business combinations. Major components of these costs include payroll and related costs for employees remaining with the Company on a transitional basis; public relations, advertising and media costs for re-branding of the combined organization; and, consulting and related fees incurred to integrate or restructure the acquired operations. Other costs include relocation and restructuring costs. These costs are expensed as incurred.

### **Income Taxes**

We account for income taxes under the liability method. Under this method, total income tax expense is the amount of income taxes expected to be payable for the current year plus the change from the beginning of the year for deferred income tax assets and liabilities established for the expected further tax consequences resulting from differences in the financial reporting and tax basis of assets and liabilities. Deferred tax assets and/or liabilities are determined by multiplying the differences between the financial reporting and tax reporting bases for assets and liabilities by the enacted tax rates expected to be in effect when such differences are recovered or settled. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date.

Tax benefits are initially recognized in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax benefit that has a greater than

50% likelihood of being realized upon ultimate settlement with the tax authority using the cumulative probability method, assuming the tax authority has full knowledge of the position and all relevant facts. Our policy is to recognize interest accrued related to unrecognized tax benefits in interest expense and penalties within the income tax provision.

### **Derivative Instruments**

We enter into derivative financial instrument contracts to minimize the variability of cash flows or income statement impact associated with the anticipated transactions being hedged or to hedge fluctuating interest rates. As changes in foreign currency or interest rate impact the value of anticipated transactions, the fair value of the forward or swap contracts also changes, offsetting foreign currency or interest rate fluctuations. Derivative instruments are recorded on the balance sheet at fair value. Changes in fair value of derivatives are recorded in current earnings or other comprehensive income, depending on whether a derivative is designated as part of a hedge transaction.

### **Share-Based Payments**

Compensation cost for all share-based payments is recorded based on the grant date fair value.

**Stock Options:** We utilize the Black-Scholes-Merton valuation model for estimating the fair value of our stock options granted. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, expected life of the award and forfeiture rate.

- **Risk-Free Interest Rate** – This is the average U.S. Treasury rate (having a term that most closely resembles the expected life of the option) at the date the option was granted.
- **Dividend Yield** – We have never declared or paid dividends on our common stock and do not anticipate declaring or paying any dividends in the foreseeable future.
- **Expected Volatility** – Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use a combination of the historical volatility of our stock price and the implied volatility of market-traded options of our stock to estimate the expected volatility assumption input to the Black-Scholes-Merton model. Our decision to use a combination of historical and implied volatility is based upon the availability of actively traded options of our stock and our assessment that such a combination is more representative of future expected stock price trends.
- **Expected Life of the Option** – This is the period of time that the options granted are expected to remain outstanding. We estimate the expected life by considering the historical exercise behavior. We use an even exercise methodology, which assumes that all vested, outstanding options are exercised uniformly over the balance of their contractual life.
- **Forfeiture Rate** – This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. We estimated the forfeiture rate based on historical forfeiture experience.

- Restricted Stock Units and Performance Stock Units: Restricted stock units and performance stock units represent rights to receive common shares at a future date. The fair market value is determined based on the number of stock units granted and the fair market value of our shares on the grant date. The fair market value at the time of the grant, less an estimate for pre-vesting forfeitures, is recognized in expense over the vesting period.

### **Cash and Cash Equivalents**

Cash and cash equivalents consist of cash on deposit in banks and other cash invested temporarily in various instruments that are short-term and highly liquid, and having an original maturity of less than 90 days at the date of purchase.

### **Short-Term Investments**

Short-term investments are classified as "available for sale" and stated at fair value in the accompanying balance sheet. Interest income is accrued when earned and changes in fair market values are reflected as unrealized gains and losses, calculated on the specific identification method, as a component of accumulated other comprehensive income. The amortization of premiums and accretion of discounts to maturity arising from acquisition are included in interest income. A decline in fair value that is judged to be other-than-temporary is accounted for as a realized loss and the write-down is included in the consolidated statements of income. Realized gains and losses, determined on a specific identification basis, on the sale of short-term investments are included in income.

### **Fair Value of Financial Instruments**

The carrying value of cash and cash equivalents, notes receivable, accounts receivable, accounts payable and accrued liabilities approximate their fair values because of the short maturities of those instruments. The carrying value of our variable rate debt and capital leases approximates their fair values because of the short maturities and / or interest rates which are comparable to those available to us on similar terms. The carrying value of the Senior Notes totaling \$ 400.0 million issued in October 2012 and further described in Note 15 approximates fair value as of December 31, 2012, as neither the Treasury rates nor credit spreads have changed significantly since the issuance date. The fair values of the notes payable to QIAGEN Finance and Euro Finance, further discussed in Note 15, were estimated by using available over-the-counter market information on the convertible bonds which were issued by QIAGEN Finance and Euro Finance, the values of which correlate to the fair value of the loan arrangements we have with QIAGEN Finance and Euro Finance which include the notes payable, the guarantee and the warrant agreement (further discussed in Note 10).

### **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 becomes questionable based on payment history or age of the receivable. Amounts determined to be uncollectible are written off against the reserve. For the years ended December 31, 2012, 2011 and 2010, write-offs of accounts receivable totaled \$ 0.2 million, \$ 0.6 million and \$ 0.8 million while provisions for doubtful accounts which were charged to expense totaled \$ 1.0 million, \$ 2.1 million and \$ 1.4 million, respectively. For all years presented, no single customer represented more than ten percent of accounts receivable or consolidated net sales.

## Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market and include material, capitalized labor and overhead costs. Inventories consisted of the following as of December 31, 2012 and 2011:

	As of December 31	
	2012	2011
<b>\$ 1,000</b>		
Raw materials	29,755	26,645
Work in process	34,231	33,757
Finished goods	71,307	71,834
<b>Total inventories</b>	<b>135,293</b>	<b>132,236</b>

## Property, Plant and Equipment

Property, plant and equipment, including equipment acquired under capital lease obligations, are stated at cost. Capitalized internal-use software costs include only those direct costs associated with the actual development or acquisition of computer software for internal use, including costs associated with the design, coding, installation and testing of the system. Costs associated with preliminary development, such as the evaluation and selection of alternatives, as well as training, maintenance and support are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets (one to 40 years). Amortization of leasehold improvements is computed on a straight-line basis over the lesser of the remaining life of the lease or the estimated useful life of the improvement asset. We have a policy of capitalizing expenditures that materially increase assets' useful lives and charging ordinary maintenance and repairs to operations as incurred. When property or equipment is disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts and any gain or loss is included in earnings.

## Acquired Intangibles and Goodwill

Acquired intangibles with alternative future uses are carried at cost less accumulated amortization and consist of licenses to technology held by third parties and other acquired intangible assets. Amortization is computed over the estimated useful life of the underlying patents, which has historically ranged from one to twenty years. Purchased intangible assets acquired in business combinations, other than goodwill, are amortized over their estimated useful lives unless these lives are determined to be indefinite. Intangibles are assessed for recoverability considering the contract life and the period of time over which the intangible will contribute to future cash flow. The unamortized cost of intangible assets, where cash flows are independent and identifiable from other assets, is evaluated periodically and adjusted, if necessary, if events and circumstances indicate that a decline in value below the carrying amount has occurred. For the years ended December 31, 2012 and 2011, we recorded intangible asset impairments of \$ 2.0 million and \$ 40.3 million, respectively, in general and administrative, restructuring, integration and other expense. There were no impairments in 2010.

Amortization expense related to developed technology and patent and license rights which have been acquired in a business combination is included in cost of sales. Amortization of trademarks,

customer base and non-compete agreements which have been acquired in a business combination is recorded in operating expense under the caption 'acquisition-related intangible amortization.' Amortization expenses of intangible assets not acquired in a business combination are recorded within the cost of sales, research and development, or sales and marketing line items based on the use of the asset.

The estimated fair values of acquired in-process research and development projects which have not reached technological feasibility at the date of acquisition are capitalized and subsequently tested for impairment through completion of the development process, at which point the capitalized amounts are amortized over their estimated useful life. If a project is abandoned rather than completed, all capitalized amounts are written off immediately.

Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired arising from business combinations. Goodwill is subject to impairment tests annually or earlier if indicators of potential impairment exist, using a fair-value-based approach. We have elected to perform our annual test for indications of impairment as of October 1st of each year. Following the annual impairment tests for the years ended December 31, 2012, 2011 and 2010, goodwill has not been impaired.

### **Investments**

We have investments in non-marketable securities issued by privately held companies. These investments are included in other long-term assets in the accompanying consolidated balance sheets and are accounted for using the equity or cost method of accounting.

Investments are evaluated at least quarterly, or sooner if impairment indicators are noted, to determine if declines in value are other-than-temporary. In making that determination, we consider all available evidence relating to the realizable value of a security. This evidence includes, but is not limited to, the following:

- adverse financial conditions of a specific issuer, segment, industry, region or other variables;
- the length of time and the extent to which the fair value has been less than cost; and
- the financial condition and near-term prospects of the issuer.

The fair values of any of our cost or equity method investments have declined below their carrying value whenever adverse events or changes in circumstances indicate that recorded values may not be recoverable. If any such decline is considered to be other than temporary (based on various factors, including historical financial results, product development activities and the overall health of the affiliate's industry), then a write-down of the investment would be recorded in operating expense to its estimated fair value. For the year ended December 31, 2012, we recorded an impairment of a cost method investment of \$3.4 million in general and administrative, restructuring, integration and other expense.

### **Impairment of Long-Lived Assets**

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or a group of assets may not be recoverable. We consider, amongst other indicators, a history of operating losses or a change in expected sales

levels to be indicators of potential impairment. Assets are grouped and evaluated for impairment at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows of other groups of assets. If an asset is determined to be impaired, the loss is measured as the amount by which the carrying amount of the asset exceeds fair value which is determined by applicable market prices, when available. When market prices are not available, we generally measure fair value by discounting projected future cash flows of the asset. Considerable judgment is necessary to estimate discounted future cash flows. Accordingly, actual results could differ from such estimates. During the years ended December 31, 2012 and 2011, in connection with our internal restructuring we recorded asset impairment charges of \$ 13.6 million and \$ 42.1 million, respectively, in general and administrative, restructuring, integration and other expenses in the accompanying consolidated statements of income related to the abandonment of certain projects. There were no material impairment losses recognized for long-lived assets during the year ended December 31, 2010.

## 4. Segment Information

Considering the acquisitions made during 2012, we determined that we still operate as one business segment in accordance with ASC Topic 280, Segment Reporting. As a result of our continued restructuring and streamlining of the growing organization, our chief operating decision maker (CODM) makes decisions with regards to business operations and resource allocation based on evaluations of QIAGEN as a whole. Accordingly, we operate as one business segment. Summarized product category and geographic information is shown in the tables below.

### Product Category Information

Net sales for the product categories are attributed based on those revenues related to sample and assay products and similarly related revenues, and revenues derived from instrumentation sales.

	2012	2011	2010
\$ 1,000			
Net sales			
Consumables and related revenues	1,085,596	1,011,863	937,714
Instrumentation	168,860	157,884	149,717
<b>Total</b>	<b>1,254,456</b>	<b>1,169,747</b>	<b>1,087,431</b>

### Geographical Information

Net sales are attributed to countries based on the location of the subsidiary generating the sale. QIAGEN operates manufacturing facilities in Germany, Switzerland, China, the United Kingdom, France 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 the countries in which the manufacturing locations are based. The intersegment portions of such net sales are excluded to derive consolidated net sales. No single customer represents more than ten percent of consolidated net sales. Our official country of domicile is the Netherlands, which reported net sales of \$ 23.7 million, \$ 23.9 million and \$ 21.5 million for the years ended 2012, 2011 and 2010, respectively, and these amounts are included in the line item Europe as shown in the table below.

\$ 1,000	2012	2011	2010
Net sales			
Americas:			
United States	518,130	466,502	472,682
Other Americas	42,921	55,137	50,912
Total Americas	561,051	521,639	523,594
Europe	459,321	444,441	398,029
Asia Pacific&Rest of World	234,084	203,667	165,808
<b>Total</b>	<b>1,254,456</b>	<b>1,169,747</b>	<b>1,087,431</b>

Long-lived assets include property, plant and equipment. The Netherlands, which is included in the balances for Europe, reported long-lived assets of \$0.4 million and \$1.1 million as of December 31, 2012 and 2011, respectively.

\$ 1,000	2012	2011
Long-lived assets		
Americas:		
United States	131,689	98,717
Other Americas	2,196	2,579
Total Americas	133,885	101,296
Europe	272,227	259,220
Asia Pacific&Rest of World	12,820	11,276
<b>Total</b>	<b>418,932</b>	<b>371,792</b>

## 5. Acquisitions

Acquisitions have been accounted for as business combinations, and the acquired companies' results have been included in the accompanying consolidated statements of income from their respective dates of acquisition. Our acquisitions have historically been made at prices above the fair value of the acquired net assets, resulting in goodwill, due to expectations of synergies of combining the businesses. These synergies include use of our existing infrastructure, such as sales force, shared service centers, distribution channels and customer relations, to expand sales of the acquired businesses' products; use of the infrastructure of the acquired businesses to cost-effectively expand sales of our products; and elimination of duplicative facilities, functions and staffing.

### 2012 Acquisitions

On May 3, 2012, we acquired AmniSure, a privately owned company that markets the AmniSure® assay for determining whether a pregnant woman is suffering rupture of fetal membranes (ROM), a condition in which fluid leaks from the amniotic sac prematurely. The acquisition of AmniSure

did not have a material business impact to net sales, net income or earnings per share, and therefore no pro forma financial information has been provided herein.

As of December 31, 2012, the final purchase price allocation is as follows:

\$ 1,000	AmniSure acquisition
<b>Purchase price:</b>	
Cash consideration	101,415
Fair value of contingent consideration	4,530
	<b>105,945</b>
<b>Allocation:</b>	
Working capital	5,297
Fixed and other long-term assets	267
Developed technology, licenses and know-how	28,941
Customer relationships	25,520
Tradenames	2,692
In-process research and development	4,522
Goodwill	44,369
Deferred tax liability on fair value of identifiable intangible assets acquired	(5,202)
Long-term liabilities assumed	(461)
	<b>105,945</b>

The weighted-average amortization period for the intangible assets is 9.5 years. The goodwill acquired is not deductible for tax purposes.

We acquired AmniSure in the second quarter of 2012. Since the acquisition date, the results of AmniSure are included in the consolidated results through December 31, 2012 and were not material. The total fair value of the contingent consideration for AmniSure of approximately \$4.5 million has been recorded as purchase price using a probability-weighted analysis of the future milestones using discount rates between 0.7% and 2.0%. Under the purchase agreement, we could be required to make additional contingent cash payments totaling \$35.0 million through 2017.

During 2012, we completed other acquisitions, including Intelligent Bio-Systems, Inc., which were not significant, either individually or in the aggregate, to the overall consolidated financial statements. The total cash paid for these acquisitions, net of cash acquired, was \$31.2 million of which an amount of \$5.2 million was retained in an escrow account to cover any claims for breach of any representations, warranties or indemnities. Certain acquisitions included contingent consideration where we are required to assess the acquisition date fair value of the contingent consideration liabilities, which is recorded as part of the purchase consideration. This is discussed further in Note 14, "Fair Value Measurements," where we assess and adjust the fair value of the contingent consideration liabilities, if necessary, until the settlement or expiration of the contingency occurs. The total fair value of the contingent consideration for these other acquisi-

tions of approximately \$ 12.0 million has been recorded as purchase price. Under the purchase agreements, we could be required to make contingent cash payments totaling \$ 12.5 million through 2016. The fair value of the contingent cash payments was determined using a discount rate of 0.7% to 1.6% and a probability regarding the accomplishment of the milestones of 95.0% to 100.0%.

Acquisition-related costs are expensed when incurred and are included in general and administrative, restructuring, integration and other in the accompanying consolidated statements of income. Acquisition-related costs for 2012 acquisitions amounted to \$ 4.5 million.

We made contingent purchase price payments totaling \$ 7.1 million in 2012 for acquisitions completed prior to 2012. The contingent purchase price payments were contractually due upon achievement of certain performance criteria of the acquired business.

### **2011 Acquisitions**

On August 29, 2011, we acquired all outstanding shares of Cellestis Ltd., a publicly listed Australian company, for \$ 372.5 million in cash. Cellestis develops and provides in vitro diagnostics and life science research products based on its proprietary QuantiFERON® technology. The technology provides information on the activity of the cell-mediated functions of the immune system from whole blood samples. By tapping into the body's memory system, this approach allows diseases to be detected much earlier than with other diagnostic methods, such as PCR. With QuantiFERON®, we added a "pre-molecular" technology that allows us to look even deeper than with DNA-based molecular testing and thereby strive to feed and drive our DNA-based molecular franchise. QuantiFERON® is a trademark of Cellestis, Ltd.

The final purchase price allocation for Cellestis did not differ from the preliminary estimates other than the recognition of approximately \$ 6.2 million of additional customer relationships, \$ 0.3 million of additional developed technology, \$ 3.9 million decrease of long-term deferred tax liability and an additional \$ 1.6 million of other opening balance sheet adjustments. The corresponding impact for these adjustments was a decrease to goodwill of \$ 12.0 million. These changes to arrive at the final purchase price allocation were not material to the consolidated financial statements. As of December 31, 2012, the final purchase price allocation for Cellestis is as follows:

	Cellestis acquisition
<b>\$ 1,000</b>	
<b>Purchase price:</b>	
Cash consideration paid	372,452
<b>Allocation:</b>	
Working capital	18,465
Fixed and other long-term assets	1,112
Developed technology, licenses and know-how	67,500
Customer relationships	48,800
Tradenames	12,000
Goodwill	258,886
Deferred tax liability on fair value of identifiable intangible assets acquired	(34,079)
Liabilities assumed	(232)
	<b>372,452</b>

The weighted-average amortization period for intangible assets is 10.0 years. The goodwill acquired is not deductible for tax purposes.

During 2011, we acquired a majority shareholding in Ipsogen S.A., a publicly listed company founded in 1999 and based in Marseille, France, that is a global leader in molecular profiling and personalized healthcare diagnostics for a broad range of applications in the field of hematology. The acquisition of Ipsogen provides QIAGEN access to a broad range of assays covering 15 biomarkers used worldwide for the diagnosis, prognosis and monitoring of patients with various blood cancers. Many of these assays also are used as companion diagnostics in personalized healthcare to make and guide treatment decisions. Many of Ipsogen's assays have CE-IVD Marking in Europe and have been developed for use on QIAGEN's Rotor-Gene Q real-time PCR system. This has the potential to enable the smooth and rapid transfer of these unique products onto QIAGEN's QIAasympathy RGQ, a novel integrated sample-to-result laboratory automation platform that includes the Rotor-Gene Q system. On July 12, 2011, we paid €40.9 million (\$57.4 million) for the initial 62.6% of Ipsogen outstanding common shares. On the acquisition date, the fair value of the noncontrolling interest was \$42.4 million and the fair value of all Ipsogen outstanding shares and other equity instruments was approximately €70.2 million (\$99.9 million). The fair value of the noncontrolling interest was based on reference to quoted market values of Ipsogen stock. The assignment of the total consideration including the fair value of the noncontrolling interest as of the date of the acquisition is shown below. Since the acquisition we have paid an additional total of \$29.8 million and hold 89.4% of the Ipsogen shares on a fully diluted basis as of December 31, 2012.

The final purchase price allocation for Ipsogen did not differ from the preliminary estimates other than the recognition of approximately \$9.0 million of additional long-term deferred tax assets related to net operating losses, \$8.1 million of additional developed technology, \$2.8 million of additional long-term deferred tax liability related to the developed technology and a net change of \$0.3 million to other intangible assets. The corresponding impact for these adjustments was a decrease to goodwill of \$14.6 million. These changes to arrive at the final purchase price allo-

cation were not material overall to the consolidated financial statements. As of December 31, 2012, the final purchase price allocation is as follows:

\$ 1,000	<b>Ipsogen acquisition</b>
<b>Purchase price:</b>	
Cash consideration paid	57,436
Fair value of remaining shares	42,437
	<b>99,873</b>
<b>Allocation:</b>	
Working capital	15,284
Deferred tax asset of acquired NOLs	8,997
Fixed and other long-term assets	2,429
Developed technology, licenses and know-how	44,500
Customer relationships	11,000
Tradenames	1,400
Goodwill	37,500
Deferred tax liability on fair value of identifiable intangible assets acquired	(19,325)
Liabilities assumed	(1,912)
	<b>99,873</b>

The weighted-average amortization period for intangible assets is 10 years. The goodwill acquired is not deductible for tax purposes.

Since the acquisition dates, the results of Cellectis and Ipsogen are included in our consolidated results through December 31, 2011. Net sales for the combined companies totaled \$ 28.6 million and net loss attributable to the owners of QIAGEN N.V. was \$ 1.7 million as of December 31, 2011. Acquisition-related costs for Cellectis and Ipsogen for the year ended December 31, 2011, amounted to \$ 5.8 million and \$ 5.6 million, respectively.

#### **Pro forma results**

The following unaudited pro forma information assumes that the Cellectis and Ipsogen occurred at the beginning of the periods presented. For the years ended December 31, 2011 and 2010, pro forma net sales would have been \$ 1,213.5 million and \$ 1,140.2 million, pro forma net income would have been \$ 91.9 million and \$ 139.2 million, and pro forma diluted net income per common share would have been \$ 0.38 and \$ 0.58, respectively. These unaudited pro forma results are intended for informational purposes only and are not necessarily indicative of the results of operations that would have occurred had the acquisitions been in effect at the beginning of the periods presented, or of future results of the combined operations.

### **Other 2011 Acquisitions**

During 2011, we completed three acquisitions which individually were not significant to the overall consolidated financial statements. The cash paid for other 2011 acquisitions, net of cash acquired, was \$47.9 million of which an amount of \$8.5 million was retained in an escrow account to cover any claims for breach of any representations, warranties or indemnities. Certain acquisitions included contingent consideration where we are required to assess the acquisition date fair value of the contingent consideration liabilities, which is recorded as part of the purchase consideration. This is discussed further in Note 14, "Fair Value Measurements," where we continuously assess and adjust the fair value of the contingent consideration liabilities, if necessary, until the settlement or expiration of the contingency occurs. The total fair value of the milestone payments of approximately \$6.9 million, determined as of the acquisition date, has been recognized as purchase price. The fair value of the milestone payments of approximately \$5.5 million was determined using a discount rate of 1.70% and a probability regarding the accomplishment of the milestones of 90% to 100%. The fair value of the milestone payments of approximately \$1.4 million was determined using a discount rate of 3.25% with the assumption that only the first milestone will be met based on the assumptions of the business plan. Under the purchase agreements at the time of acquisition, we could be required to make additional contingent cash payments totaling \$44.0 million through 2016.

### **2010 Acquisitions**

In 2010, we completed two acquisitions which individually were not significant to the overall consolidated financial statements. We acquired 100% of the shares of ESE GmbH (subsequently renamed QIAGEN Lake Constance GmbH), a privately held developer and manufacturer of UV and fluorescence optical measurement devices. ESE is based in Stockach, Germany. ESE pioneered the development and manufacturing of optical measurement systems for medical and industrial applications. The systems utilize unique, high-performance and award-winning fluorescence detection technologies integrated into compact modules. We have demonstrated that ESE's fluorescence detection systems can be used to measure signals generated by our existing testing technologies, including the HDA and tHDA isothermal assay systems. We also acquired the food market business of the Institute for Product Quality (ifp), a Berlin-based company which sells food, veterinary and environmental quality control assays. The transaction was an asset purchase of primarily patents, know-how, intellectual property rights and customer data related to the business. We have entered into license and contract manufacturing agreements with ifp under which ifp will perform the production for QIAGEN.

Aggregate consideration paid in 2010 for the acquisitions was \$22.7 million and an amount of \$2.9 million was retained in an escrow account to cover any claims for breach of any representations, warranties or indemnities. Furthermore, the purchase agreements for both acquisitions included aggregate milestone payments of up to \$8.1 million.

## 6. Restructuring

Late in 2011, we began a project to enhance productivity by streamlining the organization and freeing up resources for reallocation to strategic initiatives to help drive growth and innovation, strengthen our industry leadership position and improve longer-term profitability. This project aims to eliminate organizational layers and overlapping structures, actions that we expect will enhance our processes, speed and productivity. In 2012, we recorded pretax charges of \$41.0 million, recorded in general, administrative, restructuring and other. In 2011, we recorded pretax charges of \$74.9 million, of which \$5.5 million is recorded in cost of sales and \$69.4 million is recorded in general and administrative, restructuring and other. The pretax charges in 2012 and 2011 consisted of \$5.5 million and \$20.1 million, respectively, for workforce reductions, \$11.6 million and \$1.8 million, respectively, for fixed asset impairments, and \$2.0 million and \$40.3 million, respectively, for intangible asset abandonment charges. The intangible asset charges represent the write off of capitalized costs related to development projects which were abandoned following the decision to streamline the organization and focus development efforts on those projects with the highest potential for market acceptance and profitability. Additionally, we incurred contract termination and consulting costs of \$18.8 million and \$12.7 million for the years ended December 31, 2012 and 2011, respectively, and in 2012 we recorded \$3.1 million for lease closure costs. We expect to record additional restructuring charges in 2013 related to this program.

The specific restructuring measures and associated estimated costs were based on management's best business judgment under the existing circumstances at the time the estimates were made. If future events require changes to these estimates, such adjustments will be reflected in the applicable line item in the consolidated statement of operations.

The following table summarizes the cash components of the restructuring costs. At December 31, 2012 and 2011, restructuring accruals of \$4.9 million and \$26.9 million, respectively, were included in accrued and other liabilities in the accompanying consolidated balance sheets.

\$ 1,000	Personnel Related	Facility Related	Contract and Other Costs	Total
<b>Balance at December 31, 2011</b>	<b>19,228</b>	<b>443</b>	<b>7,238</b>	<b>26,909</b>
Additional costs in 2012	5,456	3,055	152	8,663
Payments	(21,301)	(1,032)	(6,036)	(28,369)
Release of excess accrual	(1,084)	–	(1,217)	(2,301)
Foreign currency translation adjustment	22	–	–	22
<b>Balance at December 31, 2012</b>	<b>2,321</b>	<b>2,466</b>	<b>137</b>	<b>4,924</b>

The costs in the above table do not include consulting costs associated with third-party service providers that are assisting with executing the restructuring. We accrue for consulting costs as the services are provided.

## 7. Short-term Investments

At December 31, 2012 and 2011, we had €62.5 million (\$82.5 million as of December 31, 2012) and €35.0 million (\$45.3 million as of December 31, 2011), respectively, of loan note receivables due from financial institutions. These loan receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are carried at fair market value, which is equal to the cost. These loans consist of €47.5 million which mature in 2013 and €15.0 million in 2014. All of these instruments include put option rights on at least a quarterly basis. Interest income is determined using the effective interest rate method. These loans are classified as current assets in the accompanying consolidated balance sheets since we may put the loans at our discretion.

At December 31, 2012 and 2011, we also had €6.1 million (\$8.0 million) and €7.2 million (\$9.3 million), respectively in term deposits with final maturities until December 2014. The deposits can be withdrawn at the end of each quarter without penalty and are therefore classified as current assets in the accompanying consolidated balance sheets.

For the year ended December 31, 2012 and 2011, proceeds from sales of short-term investments totaled \$6.0 million and \$242.6 million, respectively. There were no realized gains or losses during 2012 or 2011.

## 8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are summarized as follows as of December 31, 2012 and 2011:

\$ 1,000	2012	2011
Prepaid expenses	30,354	27,832
Amounts held in escrow in connection with acquisitions	7,521	7,026
Value added tax	10,221	9,488
Other receivables	7,267	14,709
	<b>55,363</b>	<b>59,055</b>

## 9. Property, Plant and Equipment

Property, plant and equipment, including equipment acquired under capital lease obligations, are summarized as follows as of December 31, 2012 and 2011:

\$ 1,000	Estimated Useful Life (in Years)	2012	2011
Land	—	15,907	15,686
Buildings and improvements	2–40	283,173	275,529
Machinery and equipment	3–20	206,871	176,662
Computer software	1–10	86,280	65,344
Furniture and office equipment	1–13	80,343	76,809
Construction in progress	—	79,402	51,827
		<b>751,976</b>	<b>661,857</b>
Less: Accumulated depreciation and amortization		(333,044)	(290,065)
<b>Property, plant and equipment, net</b>		<b>418,932</b>	<b>371,792</b>

Amortization of assets acquired under capital lease obligations is included within accumulated depreciation and amortization above for the years ended December 31, 2012 and 2011, respectively. For the years ended December 31, 2012, 2011 and 2010 depreciation and amortization expense totaled \$ 64.8 million, \$ 57.0 million and \$ 47.9 million, respectively. For the years ended December 31, 2012, 2011 and 2010 amortization expense related to computer software costs totaled \$ 8.2 million, \$ 7.5 million and \$ 4.6 million, respectively.

Repairs and maintenance expense was \$ 13.7 million, \$ 12.9 million and \$ 11.8 million in 2012, 2011 and 2010, respectively. For the years ended December 31, 2012 and 2011, construction in progress includes amounts related to ongoing software development projects and the construction of new facilities in the United States. For the years ended December 31, 2012, 2011 and 2010, interest capitalized in connection with construction projects was not significant.

## 10. Investments

We have made strategic investments in certain companies that are accounted for using the equity or cost method of accounting. The method of accounting for an investment depends on the level of influence. We monitor changes in circumstances that may require a reassessment of the level of influence. We periodically review the carrying value of these investments for impairment, considering factors such as the most recent stock transactions and book values from the recent financial statements. The fair value of cost and equity-method investments is estimated when there are identified events or changes in circumstances that may have an impact on the fair value of the investment. A summary of these equity method investments, which are included in other assets, is as follows:

\$ 1,000 Company	Ownership Percentage	Equity Investments as of December 31,		Share of Income (Loss) for the Years Ended December 31,		
		2012	2011	2012	2011	2010
PreAnalytiX GmbH	50.00%	18,182	15,723	1,972	390	2,969
QBM Cell Science	19.50%	406	395	11	(10)	11
QIAGEN Finance	100.00%	374	252	122	103	131
QIAGEN Euro Finance	100.00%	931	622	309	266	273
Pyrobett	19.00%	3,515	3,749	(234)	(178)	(73)
Dx Assays Pte Ltd	33.30%	—	—	—	—	—
Scandinavian Gene Synthesis AB	40.00%	—	15,714	(23)	23	—
Peak-Service	40.00%	20	20	—	—	—

We have a 50% interest in a joint venture company, PreAnalytiX GmbH, for which each of the joint venture partners participates 50 / 50 in all decision making activities and therefore we are not the primary beneficiary. Thus, the investment is accounted for under the equity method. 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, our maximum exposure to loss as a result of our involvement with PreAnalytiX is limited to our share of losses from the equity method investment itself.

We have a 100% interest in QIAGEN Finance (Luxembourg) S.A. (QIAGEN Finance) and QIAGEN Euro Finance (Luxembourg) S.A. (Euro Finance), companies established for the purpose of issuing convertible debt in 2004 and 2006, respectively. In August 2004, we issued \$ 150.0 million of 1.5% Senior Convertible Notes (2004 Notes) due in 2024 through QIAGEN Finance. In May 2006, we completed the offering of \$ 300.0 million of 3.25% Senior Convertible Notes (2006 Notes) due in 2026 through Euro Finance. The proceeds of the 2004 and 2006 Notes were loaned to subsidiaries within the consolidated QIAGEN N.V. group. QIAGEN N.V. has guaranteed all of these Notes, and has agreements with each of QIAGEN Finance and Euro Finance to issue common shares to the investors in the event of conversion of any of the Notes. QIAGEN Finance and Euro Finance are variable interest entities. We do not hold any variable interests in QIAGEN Finance or Euro Finance, and we are not the primary beneficiary, therefore neither of the entities is consolidated. Accordingly, the 2004 and 2006 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 and Euro Finance. QIAGEN N.V. accounts for its investments in QIAGEN Finance and Euro Finance as equity investments and accordingly records 100% of the profit or loss of QIAGEN Finance and Euro Finance in the gain or loss from equity method investees. At present, our maximum exposure to loss as a result of our involvement with QIAGEN Finance and Euro Finance is limited to our share of losses from the equity method investments.

At December 31, 2012 and 2011, we had a total of cost-method investments in non-publicly traded companies with carrying amounts of \$ 15.5 million and \$ 6.8 million, respectively, which are included in other assets. The fair-value of these cost-method investments are not estimated unless there are identified events or changes in circumstances that may have a significant adverse effect

on the fair value of the investment. For the year ended December 31, 2012, we recorded an impairment of a cost method investment of \$3.4 million in general and administrative, restructuring, integration and other expense.

During 2011, we paid \$9.7 million for a 40% share together with a \$6.7 million advance payment towards the potential future acquisition of the remaining 60% of Scandinavian Gene Synthesis AB. In 2012, we acquired the remaining shares for \$8.4 million.

In 2010, we made a \$4.0 million investment in Pyrobett, a company located in Singapore which performs research and development activities related to the development of instruments for use in life sciences.

## 11. Goodwill and Intangible Assets

The following sets forth the intangible assets by major asset class as of December 31, 2012 and 2011:

		2012		2011	
	Weighted Average Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
\$ 1,000					
<b>Amortized intangible assets:</b>					
Patent and license rights	11.7 years	304,380	(134,688)	294,854	(115,310)
Developed technology	10.0 years	678,888	(270,575)	605,847	(210,022)
Customer base, trademarks, and non-compete agreements	10.3 years	391,388	(126,743)	336,216	(92,098)
	<b>10.4 years</b>	<b>1,374,656</b>	<b>(532,006)</b>	<b>1,236,917</b>	<b>(417,430)</b>
<b>Unamortized intangible assets:</b>					
In-process research and development		11,222		—	
Goodwill		1,759,898		1,733,722	
		<b>1,771,120</b>		<b>1,733,722</b>	

Amortization expense on intangible assets totaled approximately \$133.1 million, \$110.4 million and \$94.9 million, respectively, for the years ended December 31, 2012, 2011 and 2010. In connection with the restructuring discussed more fully in Note 6, an abandonment charge of \$2.0 million and \$40.3 million related to discontinued projects was recorded in general and administrative, restructuring, integration and other in 2012 and 2011, respectively. The amortization of the in-process research and development will begin in 2013 as the projects are completed.

Amortization of intangibles for the next five years is expected to be approximately:

\$ 1,000	Amortization
<b>Years ended December 31:</b>	
2013	125,722
2014	124,836
2015	124,117
2016	121,195
2017	117,332

The changes in the carrying amount of goodwill for the years ended December 31, 2012 and 2011, are as follows:

\$ 1,000	Total
<b>Balance at December 31, 2010</b>	
Goodwill acquired during the year	1,352,281
Earn-out and milestone payments	402,575
Purchase adjustments	1,122
Effect of foreign currency translation	615
<b>Balance at December 31, 2011</b>	<b>1,733,722</b>
Goodwill acquired during the year	82,599
Earn-out and milestone payments	(36)
Purchase adjustments	(70,034)
Effect of foreign currency translation	13,647
<b>Balance at December 31, 2012</b>	<b>1,759,898</b>

The changes in the carrying amount of goodwill during the year ended December 31, 2012 resulted from the 2012 acquisitions, purchase price adjustments primarily related to the 2011 acquisitions, foreign currency translation and changes in the fair value of contingent consideration as discussed in Note 14. During 2011, changes in goodwill resulted primarily from 2011 acquisitions and foreign currency translation. Accumulated goodwill impairment totaled \$ 1.6 million as of December 31, 2012 and 2011.

We occasionally enter into transactions which include the purchase, sale, or licensing of patented or non-patented technology as well as supply agreements, particularly in the areas of Pharma and Molecular Diagnostics. The agreements may be structured such that the transaction is required to be accounted for in accordance with ASC No. 845, Nonmonetary Transactions ("ASC No. 845") and may include multiple deliverables accounted for accordance with ASC No. 605, Revenue Recognition.

During 2010, we entered into a series of transactions with a third party, under which we exchanged certain intangible assets in a nonmonetary exchange. We have accounted for this transaction under ASC No. 845, and recorded the intangible assets received at the fair value of the assets surrendered. As there is no observable market for these assets, we have performed this nonrecurring fair value measurement based on significant unobservable inputs (Level 3 as defined in Note 14). We have performed the fair value analysis using an income approach, including development of inputs such as future revenues to be generated under the assets, and future costs associated with product development, production, and distribution under the patents, in order to determine an exit price from the perspective of a market participant that holds the assets. As a result of nonmonetary transactions, we recorded intangible assets of \$30.3 million, net sales of \$11.0 million and deferred revenues of \$19.3 million. In the same series of transactions, we agreed to supply certain products and the deferred revenue will be recognized ratably in connection with the supply of the products. Through December 31, 2011, we recognized \$1.6 million of the deferred revenue. No amounts of deferred revenue were recognized during 2012.

## 12. Accrued and Other Liabilities

Accrued and other liabilities at December 31, 2012 and 2011, consist of the following:

\$ 1,000	2012	2011
Accrued expenses	62,567	82,342
Payroll and related accruals	49,563	44,421
Deferred revenue	27,296	23,793
Accrued royalties	17,600	25,659
Fair value of derivative instruments	12,911	2,492
Accrued earn-outs and milestone payments	9,806	17,470
Accrued interest on long-term debt	7,008	7,383
Preacquisition contingencies assumed in acquisition	5,493	6,203
Current portion of capital lease obligations	4,203	4,006
<b>Total accrued and other liabilities</b>	<b>196,447</b>	<b>213,769</b>

## 13. Derivatives and Hedging

### Derivatives and Hedging

In the ordinary course of business, we use derivative instruments, including swaps, forwards and/or options, to manage potential losses from foreign currency exposures and variable rate debt. The principal objective of such derivative instruments is to minimize the risks and/or costs associated with global financial and operating activities. We do not utilize derivative or other financial instruments for trading or other speculative purposes. We recognize all derivatives as either assets or liabilities on the balance sheet on a gross basis, measure those instruments at fair value and recognize the change in fair value in earnings in the period of change, unless the derivative qualifies as an effective hedge that offsets certain exposures. We do not offset the fair value of derivative instruments with cash collateral held or received from the same counterparty under a master netting arrangement.

As of December 31, 2011, all derivatives that qualified for hedge accounting were cash-flow hedges. For derivative instruments that are designated and qualify as a cash-flow hedge, the effective portion of the gain or loss on the derivative is reported as a component of other comprehensive income (loss) and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. Gains and losses on the derivative representing either hedge ineffectiveness or hedge components excluded from the assessment of effectiveness are recognized in current earnings. In 2012 and 2011, we did not record any hedge ineffectiveness related to any cash-flow hedges in earnings and did not discontinue any cash-flow hedges. The cash flows derived from derivatives, including those that are not designated as hedges, are classified in the operating section of the consolidated statements of cash flows. As of December 31, 2012 we did not have any derivatives that were accounted for as hedging instruments.

### **Foreign Currency Derivatives**

As a globally active enterprise, we are subject to risks associated with fluctuations in foreign currencies in our ordinary operations. This includes foreign currency-denominated receivables, payables, debt, and other balance sheet positions including intercompany items. We manage balance sheet exposure on a group-wide basis primarily using foreign exchange forward contracts, foreign exchange options and cross-currency swaps.

In addition, we were party to cross-currency swaps which were entered into in connection with the notes payable to Euro Finance (see Note 15) and which qualified as cash-flow hedges with a notional amount of \$120.0 million as of December 31, 2011, which matured in November 2012 and had fair market values of \$0.7 million included in prepaid and other assets and \$1.7 million included in accrued and other liabilities as of December 31, 2011 in the accompanying consolidated balance sheets.

### **Undesignated Derivative Instruments**

We are party to various foreign exchange forward and swap arrangements which had, at December 31, 2012, an aggregate notional value of approximately \$574.5 million and fair values of \$0.8 million and \$12.9 million, which are included in prepaid and other assets and accrued and other liabilities, respectively, and which expire at various dates through April 2013. The transactions have been entered into to offset the effects from short-term balance sheet exposure to foreign currency exchange risk. Changes in the fair value of these arrangements have been recognized in other (expense) income, net.

We were party to various foreign exchange forward and swap arrangements which had, at December 31, 2011, an aggregate notional value of approximately \$204.0 million and fair values of \$5.5 million and \$0.8 million, which are included in prepaid and other assets and accrued and other liabilities, respectively, and which expired at various dates through April 2012. The transactions have been used to offset the effects from short-term balance sheet exposure to foreign currency exchange risk. Changes in the fair value of these arrangements have been recognized in other (expense) income, net.

### **Interest Rate Derivatives**

We used interest rate derivative contracts on certain borrowing transactions to hedge fluctuating interest rates until October 2011. We entered into interest rate swaps in which we agreed to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional principal amount.

### Fair Values of Derivative Instruments

The following table summarizes the fair value amounts of derivative instruments reported in the consolidated balance sheets as of December 31, 2012 and 2011:

	Derivatives in Asset Positions		Derivatives in Liability Positions	
	December 31, 2012	Fair Value	December 31, 2012	Fair Value
\$ 1,000				
<b>Derivative instruments designated as hedges</b>				
Interest rate contracts	–	–	–	–
Foreign exchange contracts	–	658	–	(1,723)
<b>Total derivative instruments designated as hedges</b>	–	658	–	(1,723)
<b>Undesignated derivative instruments</b>				
Foreign exchange contracts	833	5,489	(12,911)	(769)
<b>Total derivative instruments</b>	<b>833</b>	<b>6,147</b>	<b>(12,911)</b>	<b>(2,492)</b>

### Gains and Losses on Derivative Instruments

The following tables summarize the locations and gains on derivative instruments for the years ended December 31, 2012 and 2011:

Year ended December 31, 2012	Gain (Loss) Recognized in AOCI	Location of (Gain) Loss in Income Statement	(Gain) Loss Reclassified from AOCI into Income	Gain Recognized in Income
<b>\$ 1,000</b>				
<b>Cash flow hedges</b>				
Interest rate contracts	–	Interest expense	–	–
Foreign exchange contracts	305	Other expense / income, net	781	–
<b>Total</b>	<b>305</b>		<b>781</b>	<b>–</b>
<b>Undesignated derivative instruments</b>				
Foreign exchange contracts	–	Other expense / income, net	–	(13,456)
<b>Year ended December 31, 2011</b>	<b>Gain (Loss) Recognized in AOCI</b>	<b>Location of (Gain) Loss in Income Statement</b>	<b>(Gain) Loss Reclassified from AOCI into Income</b>	<b>Loss Recognized in Income</b>
<b>\$ 1,000</b>				
<b>Cash flow hedges</b>				
Interest rate contracts	2,721	Interest expense	–	NA
Foreign exchange contracts	2,696	Other expense / income, net	(3,961)	NA
<b>Total</b>	<b>5,417</b>		<b>(3,961)</b>	<b>NA</b>
<b>Undesignated derivative instruments</b>				
Foreign exchange contracts	NA	Other expense / income, net	NA	14,194

NA – Not applicable

The amounts noted in the table above for accumulated other comprehensive income (AOCI) do not include any adjustment for the impact of deferred income taxes.

## 14. Fair Value Measurements

Assets and liabilities are measured at fair value according to a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

Level 1. Observable inputs, such as quoted prices in active markets;

Level 2. Inputs, other than the quoted price in active markets, that are observable either directly or indirectly; and

Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Our assets and liabilities measured at fair value on a recurring basis consist of short-term investments, which are classified in Level 1 and Level 2 of the fair value hierarchy, derivative contracts used to hedge currency and interest rate risk, which are classified in Level 2 of the fair value hierarchy, and contingent consideration accruals, which are classified in Level 3 of the fair value hierarchy, and are shown in the tables below. In determining fair value for Level 2 instruments, we apply a market approach, using quoted active market prices relevant to the particular instrument under valuation, giving consideration to the credit risk of both the respective counterparty to the contract and the Company. To determine our credit risk we estimated our credit rating by benchmarking the price of outstanding debt to publicly-available comparable data from rated companies. Using the estimated rating, our credit risk was quantified by reference to publicly-traded debt with a corresponding rating. We value contingent consideration liabilities using Level 3 unobservable inputs, applying the income approach, such as the discounted cash flow technique, or the probability-weighted scenario method. Contingent consideration arrangements obligate us to pay the sellers of an acquired entity if specified future events occur or conditions are met such as the achievement of technological or revenue milestones. We use various key assumptions, such as the probability of achievement of the milestones and the discount rate, to represent the non-performing risk factors and time value when applying the income approach. We regularly review the fair value of the contingent consideration, and reflect any change in the accrual in the consolidated statements of income in the line items commensurate with the underlying nature of milestone arrangements.

The following table presents our fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2012 and 2011:

	As of December 31, 2012				As of December 31, 2011			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>\$ 1,000</b>								
<b>Assets:</b>								
Short-term investments	7,989	82,462	–	90,451	9,290	45,287	–	54,577
Foreign exchange contracts	–	833	–	833	–	6,147	–	6,147
	<b>7,989</b>	<b>83,295</b>	<b>–</b>	<b>91,284</b>	<b>9,290</b>	<b>51,434</b>	<b>–</b>	<b>60,724</b>
<b>Liabilities:</b>								
Foreign exchange contracts	–	12,911	–	12,911	–	2,492	–	2,492
Contingent consideration	–	–	18,983	18,983	–	–	38,646	38,646
	<b>–</b>	<b>12,911</b>	<b>18,983</b>	<b>31,894</b>	<b>–</b>	<b>2,492</b>	<b>38,646</b>	<b>41,138</b>

For liabilities with Level 3 inputs, the following table summarizes the activity as of December 31, 2012:

	<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Contingent Consideration</b>
<b>\$ 1,000</b>	
<b>Balance at December 31, 2010</b>	<b>22,510</b>
Additions from acquisitions	24,885
Payments	(9,065)
Loss included in earnings	253
Foreign currency translation	63
<b>Balance at December 31, 2011</b>	<b>38,646</b>
Additions from acquisitions	16,875
Payments	(6,008)
Gain included in earnings	(11,463)
Reversals	(19,129)
Foreign currency translation	62
<b>Ending balance at December 31, 2011</b>	<b>18,983</b>

For the year ended December 31, 2012, the gain of \$ 11.5 million was recognized in earnings as follows: \$ 6.7 million in cost of sales and \$ 4.8 million in general and administrative, restructuring, integration and other. During 2012, a reduction in the fair value of contingent consideration of \$ 19.1 million was recorded against goodwill shortly after the acquisition and during the measurement period.

The carrying values of financial instruments, including cash and equivalents, accounts receivable, accounts payable and other accrued liabilities, approximate their fair values due to their short-term maturities. The estimated fair value of long-term debt as disclosed in Note 15 was based on current interest rates for similar types of borrowings. The estimated fair values may not represent actual values of the financial instruments that could be realized as of the balance sheet date or that will be realized in the future. There were no fair value adjustments in the years ended December 31, 2012 and 2011 for nonfinancial assets or liabilities required to be measured at fair value on a nonrecurring basis other than the impairment of a cost-method investment as discussed in Note 10.

## 15. Lines of Credit and Debt

The credit facilities available at December 31, 2012 total € 438.0 million (approximately \$ 577.9 million). This includes a € 400.0 million syndicated multi-currency revolving credit facility expiring December 2016 of which no amounts were utilized at December 31, 2012, and four other lines of credit amounting to € 38.0 million with no expiration date, none of which were utilized as of December 31, 2012. The € 400.0 million facility can be utilized in euro, U.K. pound or U.S. dollar and bears interest of 0.8% to 2.35% above three months EURIBOR, or LIBOR in relation to any loan not in euro, and is offered with interest periods of one, two, three, six or twelve months. The commitment fee is calculated based on 35% of the applicable margin. In 2012, \$ 1.1 million of commitment fees were paid. The revolving facility agreement contains certain financial and non-financial covenants, including but not limited to restrictions on the encumbrance of assets and the maintenance of certain financial ratios. We were in compliance with these covenants at December 31, 2012. The credit facilities are for general corporate purposes.

In October 2012, we completed a private placement through the issuance of new senior unsecured notes at a total amount of \$ 400 million with a weighted average interest rate of 3.66% (settled on October 16, 2012). The notes were issued in three series: (1) \$ 73 million 7-year term due in 2019 (3.19%); (2) \$ 300 million 10-year term due in 2022 (3.75%); and (3) \$ 27 million 12-year term due in 2024 (3.90%). We paid \$ 2.1 million in debt issue costs which will be amortized through interest expense over the lifetime of the notes. The note purchase agreement contains certain financial and non-financial covenants, including but not limited to, restrictions on priority indebtedness and the maintenance of certain financial ratios. We were in compliance with these covenants at December 31, 2012. The carrying values of these Senior Notes totaling \$ 400.0 million approximates fair value as of December 31, 2012, as neither the Treasury rates nor credit spreads have changed significantly since the issuance date in October 2012.

Approximately € 170 million (approximately \$ 220 million) of proceeds from the notes were used to repay amounts outstanding under our short-term revolving credit facility. The remainder of the proceeds provides additional resources to support QIAGEN's longer-term business expansion.

At December 31, 2012, total long-term debt was approximately \$ 847.0 million, \$ 0.9 million of which is current. We believe that funds from operations, existing cash and cash equivalents, short-term investments and availability of financing facilities as needed, will be sufficient to fund our debt repayments coming due in 2013.

	As of December 31	
	2012	2011
<b>\$ 1,000</b>		
Notes payable to QIAGEN Euro Finance bearing interest at an effective rate of 3.7% due in May 2026	300,000	300,000
Notes payable to QIAGEN Finance bearing interest at an effective rate of 1.8% due in February 2024	145,000	145,000
3.19% Series A Senior Notes due October 16, 2019	73,000	–
3.75% Series B Senior Notes due October 16, 2022	300,000	–
3.90% Series C Senior Notes due October 16, 2024	27,000	–
Other notes payable bearing interest up to 6.28 % and due through November 2015	1,992	2,622
<b>Total long-term debt</b>	<b>846,992</b>	<b>447,622</b>
Less current portion	948	1,617
<b>Long-term portion</b>	<b>846,044</b>	<b>446,005</b>

Future principal maturities of long-term debt as of December 31, 2012, are as follows:

<b>\$ 1,000</b>	
<b>Years ending December 31</b>	
2013	948
2014	396
2015	648
2016	–
2017	–
Thereafter	845,000
	<b>846,992</b>

Interest expense on long-term debt was \$ 17.4 million, \$ 22.1 million and \$ 24.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In May 2006, we completed the offering of \$ 300 million of 3.25% Senior Convertible Notes due in 2026 (2006 Notes) through an unconsolidated subsidiary, QIAGEN Euro Finance. The net proceeds of the 2006 Notes are loaned by Euro Finance to consolidated subsidiaries and at December 31, 2012 and 2011, \$ 300 million is included in long-term debt for the loan amounts payable to Euro Finance. These long-term notes payable to Euro Finance have an effective interest rate of 3.7% and were originally due in December 2014. In 2012, we refinanced the \$ 300 million note with QIAGEN Euro Finance and under the new terms the debt is due in May 2026. Interest is payable semi-annually in May and November. The 2006 Notes were issued at 100% of principal value, and are convertible into 15.0 million common shares at the option of the hold-

ers upon the occurrence of certain events, at a price of \$ 20.00 per share, subject to adjustment. QIAGEN N.V. has an agreement with Euro Finance to issue shares to the investors in the event of conversion. This subscription right, along with the related receivable, is recorded at fair value in the equity of QIAGEN N.V. as paid-in capital. The 2006 Notes cannot be called for the first 7 years and are callable thereafter subject to a provisional call trigger of 130% of the conversion price. In addition, the holders of the 2006 Notes may require QIAGEN to repurchase all or a portion of the outstanding Notes for 100% of the principal amount, plus accrued interest, on May 16, 2013, 2017 and 2022. Based on an estimation using available over-the-counter market information on the convertible bond issued by QIAGEN Euro Finance, the fair value of the 2006 Notes at December 31, 2012 was \$ 358.4 million. We have reserved 15.0 million common shares for issuance in the event of conversion.

In August 2004, we completed the sale of \$ 150 million of 1.5% Senior Convertible Notes due in 2024 (2004 Notes), through our unconsolidated subsidiary QIAGEN Finance. The net proceeds of the Senior Convertible Notes are loaned by QIAGEN Finance to consolidated subsidiaries with an effective interest rate of 1.8% and at December 31, 2012 and 2011, \$ 145 million is included in long-term debt for the loan amounts payable to QIAGEN Finance. The notes are due in February 2024. Interest is payable semi-annually in February and August. The 2004 Notes were issued at 100% of principal value, and are convertible into 11.5 million common shares at the option of the holders upon the occurrence of certain events at a price of \$ 12.6449 per share, subject to adjustment. QIAGEN N.V. has an agreement with QIAGEN Finance to issue shares to the investors in the event of conversion. This subscription right, along with the related receivable, is recorded at fair value in the equity of QIAGEN N.V. as paid-in capital. The 2004 Notes may be redeemed, in whole or in part, at QIAGEN's option on or after August 18, 2011, at 100% of the principal amount, provided that the actual trading price of our common shares exceeds 120% of the conversion price for twenty consecutive trading days. In addition, the holders of the 2004 Notes may require QIAGEN to repurchase all or a portion of the outstanding 2004 Notes for 100% of the principal amount, plus accrued interest, on August 18, 2014 and 2019. Based on an estimation using available over-the-counter market information on the convertible bond issued by QIAGEN Finance, the fair value of the 2004 Notes at December 31, 2012 was \$ 209.7 million. We have reserved 11.5 million common shares for issuance in the event of conversion.

## 16. Income Taxes

Income before provision for income taxes for the years ended December 31, 2012, 2011 and 2010 consisted of:

\$ 1,000	2012	2011	2010
Pretax income in The Netherlands	27,222	30,232	55,431
Pretax income from foreign operations	117,931	65,980	117,690
	<b>145,153</b>	<b>96,212</b>	<b>173,121</b>

The provisions for income taxes for the years ended December 31, 2012, 2011 and 2010 are as follows:

\$ 1,000	2012	2011	2010
<b>Current</b>			
The Netherlands			
The Netherlands	3,271	6,752	12,265
Foreign	35,112	26,372	36,487
	<b>38,383</b>	<b>33,124</b>	<b>48,752</b>
<b>Deferred</b>			
The Netherlands	-	-	-
Foreign	(22,767)	(31,861)	(19,942)
	<b>(22,767)</b>	<b>(31,861)</b>	<b>(19,942)</b>
<b>Total provision for income taxes</b>	<b>15,616</b>	<b>1,263</b>	<b>28,810</b>

The Netherlands statutory income tax rate for the years ended December 31, 2012, 2011 and 2010 was 25%, 25% and 25.5%. The principal items comprising the differences between income taxes computed at the Netherlands statutory rate and the effective tax rate for the years ended December 31, 2012, 2011 and 2010 are as follows:

\$ 1,000	2012	2011	2010			
	Amount	%	Amount	%	Amount	%
Income taxes at The Netherlands statutory rate	36,288	25.0	24,053	25.0	44,146	25.5
Earnings of subsidiaries taxed at different rates	5,180	3.6	3,204	3.3	7,710	4.5
Tax impact from permanent items	4,854	3.4	5,989	6.2	3,295	1.9
Tax impact from tax exempt income	(36,969)	(25.5)	(23,382)	(24.3)	(10,283)	(6.0)
Tax contingencies, net	2,729	1.9	(1,675)	(1.7)	(1,269)	(0.7)
Taxes due to changes in tax rates	(1,086)	(0.8)	(3,521)	(3.7)	(1,400)	(0.8)
Taxes due to changes in tax laws	2,697	1.9	-	-	-	-
Restructuring	-	-	-	-	(12,903)	(7.5)
Prior year taxes	2,805	1.9	(2,632)	(2.7)	476	0.3
Other items, net	(882)	(0.6)	(773)	(0.8)	(962)	(0.6)
<b>Total provision for income taxes</b>	<b>15,616</b>	<b>10.8</b>	<b>1,263</b>	<b>1.3</b>	<b>28,810</b>	<b>16.6</b>

We conduct business globally and, as a result, file numerous consolidated and separate income tax returns in the Netherlands, Germany, Switzerland and the U.S. federal jurisdiction, as well as in various other state and foreign jurisdictions. In the normal course of business, we are subject to examination by taxing authorities throughout the world. Tax years in the Netherlands are open since 2000 for income tax examinations by tax authorities. Our subsidiaries, with few exceptions, are no longer subject to income tax examinations by tax authorities for years before 2008. The U.S. consolidated group is subject to federal and most state income tax examinations by tax authorities beginning with the year ending December 31, 2008 through the current period.

During 2011, the tax authorities audited the income tax returns of our German subsidiaries for the tax years 2006 through 2009. The outcome of the audit resulted in a current tax liability of \$ 5.3 million primarily related to the timing of certain deductions. As such, a deferred tax asset and deferred tax benefit was recorded that substantially offset the current year liability and expense. As a result of the audit being settled in 2011, the Company released \$ 2.3 million of tax reserves through income tax expense.

We do not currently anticipate that our existing reserves related to uncertain tax positions as of December 31, 2012, will significantly increase or decrease during the twelve-month period ending December 31, 2013; however, various events could cause our current expectations to change in the future. The majority of these uncertain tax positions, if ever recognized in the financial statements, would be recorded in the statement of operations as part of the income tax provision.

Changes in the gross amount of unrecognized tax benefits are as follows:

\$ 1,000	Unrecognized Tax Benefits
<b>Balance at December 31, 2010</b>	<b>8,673</b>
Additions based on tax positions related to the current year	757
Additions for tax positions of prior years	31
Settlements with taxing authorities	(2,257)
Reductions due to lapse of statute of limitations	(207)
Decrease from currency translation	(62)
<b>Balance at December 31, 2011</b>	<b>6,935</b>
Additions based on tax positions related to the current year	819
Additions for tax positions of prior years	3,608
Reductions due to lapse of statute of limitations	(691)
Increase from currency translation	104
<b>Balance at December 31, 2012</b>	<b>10,775</b>

At December 31, 2012 and 2011, our net unrecognized tax benefits totaled approximately \$ 8.8 million and \$ 6.3 million, respectively, of which \$ 8.8 million and \$ 6.3 million in benefits, if recognized, would favorably affect our effective tax rate in any future period. It is possible that approximately \$ 2.4 million of the unrecognized tax benefits may be released during the next 12 months due to lapse of statute of limitations or settlements with tax authorities.

Our policy is to recognize interest accrued related to unrecognized tax benefits in interest expense and penalties within tax provision expense. At December 31, 2012 and 2011, we have net interest expense and penalties of \$ 2.8 million and \$ 0.1 million, respectively. At December 31, 2012 and 2011, we have accrued interest of \$ 3.0 million and \$ 0.5 million, respectively, that are not included in the table above.

We have recorded net deferred tax liabilities of \$ 165.0 million and \$ 181.5 million at December 31, 2012 and 2011, respectively. The 2011 deferred taxes have been adjusted to correctly reflect as current or non-current and to net deferred tax positions within the same tax jurisdictions. These

balance sheet reclassifications have no impact on retained earnings. The components of the net deferred tax liability at December 31, 2012, and December 31, 2011, are as follows:

\$ 1,000	2012		2011	
	Deferred Tax Assets	Deferred Tax Liability	Deferred Tax Assets	Deferred Tax Liability
Net operating loss carry forwards	17,664	-	10,389	-
Accrued and other liabilities	21,412	(552)	25,981	(65)
Inventories	2,991	(1,410)	3,106	(1,578)
Allowance for bad debts	687	(600)	726	(471)
Currency revaluation	266	(746)	-	(546)
Depreciation and amortization	606	(10,027)	124	(19,854)
Capital lease	2,149	-	2,392	-
Tax credits	611	-	6,848	-
Unremitted profits and earnings	-	(1,215)	-	(1,175)
Intangibles	5,270	(220,880)	2,523	(218,027)
Equity awards	10,082	-	7,289	-
Other	10,460	(1,314)	6,553	(1,432)
Valuation allowance	(442)	-	(4,260)	-
	<b>71,756</b>	<b>(236,744)</b>	<b>61,671</b>	<b>(243,148)</b>
<b>Net deferred tax liabilities</b>		<b>(164,988)</b>		<b>(181,477)</b>

At December 31, 2012 and 2011, we had \$ 58.7 million and \$ 39.4 million in total foreign net operating losses. At December 31, 2012 and 2011, we had \$ 13.5 million and \$ 5.1 million of U.S. federal net operating loss (NOL) carryforwards. At December 31, 2012, the entire NOLs in the U.S. are subject to limitations under Section 382 of the Internal Revenue Code but all losses subject to IRC 382 limitation are expected to be utilized before they expire. The net operating losses in the U.S. will expire beginning December 31, 2021 through December 31, 2031. As of December 31, 2012 and 2011, we had other foreign NOL carryforwards totaling approximately \$ 45.2 million and \$ 34.3 million, respectively. These NOLs were primarily generated from acquisitions and operating losses from our subsidiaries. A portion of the foreign net operating losses will be expiring beginning December 31, 2013. The valuation allowance amounts for the years ended December 31, 2012 and 2011 are \$ 0.4 million and \$ 4.3 million, respectively. We had a release of the valuation allowance of \$ 3.9 million in 2012 as an adjustment to goodwill related to a deferred tax asset from a 2009 acquisition. In 2011, we had a decrease of valuation allowance of \$ 1.1 million from the deferred tax assets that were used to offset current tax liability.

As of December 31, 2012, a provision has not been made for residual Netherlands income taxes on the undistributed earnings of the majority of our foreign subsidiaries as these earnings are considered to be either permanently reinvested or can be repatriated tax free. These earnings retained by subsidiaries and equity accounted investments amounted to \$ 185.0 million at December 31, 2012. We have \$ 18.0 million of undistributed earnings that we do not consider permanently reinvested and have recorded deferred income taxes or withholding taxes at

December 31, 2012 and December 31, 2011, of approximately \$ 1.2 million. There are no income tax consequences regarding payment of dividends to our shareholders. To date, we have never paid dividends.

## 17. Accumulated Other Comprehensive Income

The following table is a summary of the components of accumulated other comprehensive income at December 31:

\$ 1,000	2012	2011
Net unrealized loss on hedging contracts, net of tax of \$ 0.1 million in 2011	–	(762)
Net unrealized (loss) gain on pension, net of tax	(483)	115
Foreign currency effects from intercompany long-term investment transactions, net of tax of \$ 4.4 million and \$ 4.9 million in 2012 and 2011, respectively	5,954	7,369
Foreign currency translation adjustments	38,520	9,182
<b>Accumulated other comprehensive income</b>	<b>43,991</b>	<b>15,904</b>

## 18. Share Repurchase Program

In 2012, the Supervisory Board approved a program authorizing management to purchase up to a total of \$ 100 million of our common shares (excluding transaction costs). Through December 31, 2012, a total of 1.9 million QIAGEN shares were repurchased for approximately \$ 35.7 million, in total. We intend to complete the share repurchase program in 2013. The cost of repurchased shares is included in treasury stock and reported as a reduction in total equity when a repurchase occurs. Repurchased shares will be held in treasury in order to satisfy various obligations, which include exchangeable debt instruments and employee share-based remuneration plans.

## 19. Earnings per Common Share

We present basic and diluted earnings per share. Basic earnings per share is calculated by dividing the net income attributable to the owners of QIAGEN N.V. by the weighted average number of common shares outstanding. Diluted earnings per share reflect the potential dilution that would occur if all “in the money” securities to issue common shares were exercised. The following schedule summarizes the information used to compute earnings per common share:

	Years ended December 31		
	2012	2011	2010
<b>\$ 1,000, except per share data</b>			
Net income attributable to the owners of QIAGEN N.V.	129,506	96,038	144,311
Weighted average number of common shares used to compute basic net income per common share	235,582	233,850	232,635
Dilutive effect of stock options and restrictive stock units	2,341	2,876	2,843
Dilutive effect of outstanding warrant shares	2,823	2,338	5,005
<b>Weighted average number of common shares used to compute diluted net income per common share</b>	<b>240,746</b>	<b>239,064</b>	<b>240,483</b>
<b>Outstanding options and awards having no dilutive effect, not included in above calculation</b>	<b>2,906</b>	<b>3,995</b>	<b>2,152</b>
<b>Outstanding warrants having no dilutive effect, not included in above calculation</b>	<b>23,644</b>	<b>23,591</b>	<b>21,462</b>
<b>Basic earnings per common share attributable to the owners of QIAGEN N.V.</b>	<b>0.55</b>	<b>0.41</b>	<b>0.62</b>
<b>Diluted earnings per common share attributable to the owners of QIAGEN N.V.</b>	<b>0.54</b>	<b>0.40</b>	<b>0.60</b>

## 20. Commitments and Contingencies

### Lease Commitments

We lease facilities and equipment under operating lease arrangements expiring in various years through 2022. Certain rental commitments provide for escalating rental payments or have renewal options extending through various years. Certain facility and equipment leases constitute capital leases expiring in various years through 2018. The accompanying consolidated financial statements include the assets and liabilities arising from these capital lease obligations. Rent expense under operating lease agreements was \$ 21.5 million, \$ 20.3 million and \$ 17.9 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Minimum future obligations under capital and operating leases at December 31, 2012 are as follows:

	Capital Leases	Operating Leases
<b>\$ 1,000</b>		
2013	5,396	16,309
2014	5,304	11,389
2015	5,290	9,834
2016	3,998	5,879
2017	1,429	3,234
Thereafter	1,429	7,809
	<b>22,846</b>	<b>54,454</b>
Less: Amount representing interest	(2,958)	
	19,888	
Less: Current portion	(4,203)	
<b>Long-term portion</b>	<b>15,685</b>	

### Licensing and Purchase Commitments

We have licensing agreements with companies, universities and individuals, some of which require certain up-front payments. Royalty payments are required on net product sales ranging from one to 25% of covered products or based on quantities sold. Several of these agreements have minimum royalty requirements. The accompanying consolidated financial statements include accrued royalties relating to these agreements in the amount of \$ 17.6 million and \$ 25.7 million at December 31, 2012 and 2011, respectively. Royalty expense relating to these agreements amounted to \$ 52.5 million, \$ 43.3 million, and \$ 45.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. Royalty expense is primarily recorded in cost of sales, with a small portion recorded as research and development expense depending on the use of the technology under license. Some of these agreements also have minimum raw material purchase requirements and requirements to perform specific types of research.

At December 31, 2012, we had commitments to purchase goods or services, and for future minimum guaranteed royalties. They are as follows:

\$ 1,000	Purchase Commitments	License & Royalty Commitments
2013	54,754	9,224
2014	4,124	3,762
2015	1,339	1,773
2016	152	1,798
2017	–	1,799
Thereafter	–	2,905
	<b>60,369</b>	<b>21,261</b>

### Contingent Consideration Commitments

Pursuant to the purchase agreements for certain acquisitions, as discussed more fully in Note 5, we could be required to make additional contingent cash payments totaling up to \$ 134.2 million based on the achievement of certain revenue and operating results milestones as follows: \$ 18.9 million in 2013, \$ 23.4 million in 2014, \$ 16.3 million in 2015, \$ 17.5 million in 2016, \$ 7.0 million in 2017, and \$ 51.1 million, payable in any 12-month period from now until 2017 based on the accomplishment of certain revenue targets, the launch of certain products or the grant of certain patent rights. Of the \$ 134.2 million total contingent obligation, we have assessed the fair value at December 31, 2012, to be \$ 19.0 million, where \$ 9.8 million and \$ 9.2 million are included in accrued and other liabilities and other long-term liabilities, respectively.

### Employment Agreements

Certain of our employment contracts contain provisions which guarantee the payments of certain amounts in the event of a change in control, as defined in the agreements, or if the executive is terminated for reasons other than cause, as defined in the agreements. At December 31, 2012, the commitment under these agreements totaled \$ 15.3 million.

### Contingencies

In the ordinary course of business, we provide a warranty to customers that our products are free of defects and will conform to published specifications. Generally, the applicable product warranty period is one year from the date of delivery of the product to the customer or of site accep-

tance, if required. Additionally, we typically provide limited warranties with respect to our services. From time to time, we also make other warranties to customers, including warranties that our products are manufactured in accordance with applicable laws and not in violation of third-party rights. We provide for estimated warranty costs at the time of the product sale. We believe our warranty reserves as of December 31, 2012 and 2011 appropriately reflect the estimated cost of such warranty obligations.

#### **Preacquisition Contingencies**

In connection with certain acquisitions, amounts were paid into escrow accounts to cover preacquisition contingencies assumed in the acquisition. The escrow amounts expected to be claimed by QIAGEN are recorded as an asset in prepaid and other expenses and amount to \$7.5 million and \$7.0 million as of December 31, 2012 and 2011, respectively. In addition, we have recorded \$5.5 million and \$6.2 million for preacquisition contingencies as a liability under accrued and other liabilities as of December 31, 2012 and 2011, respectively.

#### **Litigation**

From time to time, we may be party to legal proceedings incidental to our business. As of December 31, 2012, certain claims, suits or legal proceedings arising out of the normal course of business have been filed or were pending against QIAGEN or its subsidiaries. These matters have arisen in the ordinary course and conduct of business, as well as through acquisition. Although it is not possible to predict the outcome of such litigation, we assess the degree of probability and evaluate the reasonably possible losses that we could incur as a result of these matters. We accrue for any estimated loss when it is probable that a liability has been incurred and that the amount of the probable loss can be estimated. Based on the facts known to QIAGEN and after consultation with legal counsel, management believes that such litigation will not have a material adverse effect on QIAGEN's financial position or results of operations.

## **21. Share-Based Compensation**

We adopted the QIAGEN N.V. Amended and Restated 2005 Stock Plan (the Plan) in 2005. The Plan allows for the granting of stock rights and incentive stock options, as well as non-qualified options, stock grants and stock-based awards, generally with terms of up to 10 years, subject to earlier termination in certain situations. Generally, options vest over a three-year period. The vesting and exercisability of certain stock rights will be accelerated in the event of a Change of Control, as defined in the Plan. To date, all option grants have been at the market value on the grant date or at a premium above the closing market price on the grant date. We issue new common shares to satisfy option exercises and had approximately 19.8 million Common Shares reserved and available for issuance under this plan at December 31, 2012.

In connection with the 2007 acquisition of Digene Corporation, we assumed three additional equity incentive plans. No new grants will be made under these plans. We had approximately 0.1 million common shares reserved and available for issuance under these plans at December 31, 2012.

#### **Stock Options**

During the years ended December 31, 2012 and 2011, we granted 592,829 and 601,897 stock options, respectively. The following are the weighted-average assumptions used in valuing the stock options granted to employees for the years ended December 31, 2012, 2011 and 2010:

	2012	2011	2010
Stock price volatility	34%	34%	31%
Risk-free interest rate	0.82%	1.88%	2.12%
Expected life (in years)	4.89	4.97	4.84
Dividend rate	0%	0%	0%
Forfeiture rate	5.9%	6.1%	7.0%

A summary of the status of employee stock options as of December 31, 2012 and changes during the year then ended is presented below:

	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value (\$ 1,000)
<b>All employee options</b>				
Outstanding at January 1, 2012	6,527	\$ 13.61		
Granted	593	\$ 16.00		
Exercised	(1,444)	\$ 11.53		
Forfeited	(82)	\$ 18.90		
Expired	(261)	\$ 17.64		
<b>Outstanding at December 31, 2012</b>	<b>5,333</b>	<b>\$ 14.16</b>	<b>4.09</b>	<b>25,006</b>
<b>Exercisable at December 31, 2012</b>	<b>4,252</b>	<b>\$ 13.18</b>	<b>2.91</b>	<b>23,664</b>
<b>Vested and expected to vest at December 31, 2012</b>	<b>5,257</b>	<b>\$ 14.12</b>	<b>4.01</b>	<b>24,886</b>

Generally, stock option grants are valued as a single award with a single average expected term and are amortized over the vesting period. The weighted-average grant-date fair value of options granted during the years ended December 31, 2012, 2011, and 2010 was \$ 4.80, \$ 6.49 and \$ 6.42, respectively. The total intrinsic value of options exercised during the years ended December 31, 2012 and 2011 was \$ 7.2 million and \$ 3.7 million, respectively. At December 31, 2012, the unrecognized share-based compensation expense related to employee stock option awards including estimated forfeitures is approximately \$ 3.5 million and will be recognized over a weighted average period of approximately 1.66 years.

At December 31, 2012, 2011 and 2010, options were exercisable with respect to 4.3 million, 5.5 million and 6.4 million common shares at a weighted average price of \$ 13.18, \$ 12.37 and \$ 12.93 per share, respectively. The options outstanding at December 31, 2012 expire in various years through 2022.

### Stock Units

Stock units represent rights to receive common shares at a future date and include restricted stock units which are subject to time-vesting only and performance stock units which include performance conditions in addition to time-vesting. There is no exercise price and the fair market value at the time of the grant is recognized over the requisite vesting period, generally 10 years. The fair market value is determined based on the number of restricted stock units granted and the market value of our shares on the grant date. Pre-vesting forfeitures were estimated to be approximately 7.1%. At December 31, 2012, there was \$ 67.6 million remaining in unrecognized compensation cost including estimated forfeitures related to these awards, which is expected to be

recognized over a weighted average period of 2.9 years. The weighted average grant date fair value of stock units granted during the year ended December 31, 2012 was \$ 15.80. The total fair value of stock units that vested during the years ended December 31, 2012 and 2011, was \$ 13.3 million and \$ 8.8 million, respectively.

A summary of stock units as of December 31, 2012 and changes during the year are presented below:

<b>Stock Units</b>	<b>Stock Units in thousands</b>	<b>Weighted Average Contractual Term</b>	<b>Aggregate Intrinsic Value \$ 1,000</b>
Outstanding at January 1, 2012	5,651		
Granted	2,574		
Vested	(831)		
Forfeited	(473)		
<b>Outstanding at December 31, 2012</b>	<b>6,921</b>	<b>2.85</b>	<b>125,602</b>
<b>Vested and expected to vest at December 31, 2012</b>	<b>5,732</b>	<b>2.74</b>	<b>104,029</b>

### Compensation Expense

Share-based compensation expense before taxes for the years ended December 31, 2012, 2011 and 2010 totaled approximately \$ 25.4 million, \$ 19.5 million and \$ 13.6 million, respectively, as shown in the table below. No share-based compensation cost was capitalized in inventory in 2012, 2011 or 2010 as the amounts were not material. The excess tax benefit realized for the tax deductions of the share-based payment arrangements totaled \$ 1.5 million, \$ 4.2 million and \$ 2.0 million, respectively, for the years ended December 31, 2012, 2011 and 2010.

<b>Compensation expense \$ 1,000</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>
Cost of sales	2,328	1,672	932
Research and development	4,167	3,055	2,087
Sales and marketing	6,123	4,285	2,885
General and administrative	12,737	10,528	7,688
<b>Share-based compensation expense</b>	<b>25,355</b>	<b>19,540</b>	<b>13,592</b>

## 22. Employee Benefits

We maintain various benefit plans, including defined contribution and defined benefit plans. Our U.S. defined contribution plan is qualified under Section 401(k) of the Internal Revenue Code, and covers substantially all U.S. employees. Participants may contribute a portion of their compensation not exceeding a limit set annually by the Internal Revenue Service. This plan includes a provision for us to match a portion of employee contributions. Total expense under the 401(k) plans, including the plans acquired via business acquisitions, was \$ 3.1 million, \$ 2.3 million and \$ 2.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. We also have a defined contribution plan which covers certain executives. We make matching contributions up to an established maximum. Matching contributions made to the plan, and expensed, totaled approximately \$ 0.3 million in each year ended December 31, 2012, 2011 and 2010.

We have four defined benefit, non-contributory retirement or termination plans that cover certain employees in Germany, France, Japan and Italy. These defined benefit plans provide benefits to covered individuals satisfying certain age and service requirements. For certain plans, we calculate the vested benefits to which employees are entitled if they separate immediately. The benefits accrued on a pro-rata basis during the employees' employment period are based on the individuals' salaries, adjusted for inflation. The liability under the defined benefit plans was \$4.0 million at December 31, 2012, and \$2.9 million at December 31, 2011, and is included as a component of other long-term liabilities on the consolidated balance sheets.

## 23. Related Party Transactions

We have a 100% interest in QIAGEN Finance (Luxembourg) S.A. (QIAGEN Finance) and QIAGEN Euro Finance (Luxembourg) S.A. (Euro Finance), which were established for the purpose of issuing convertible debt. As discussed in Note 10, QIAGEN Finance and Euro Finance are variable interest entities for which we do not hold any variable interests and are not the primary beneficiary, thus they are 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 and Euro Finance. As of December 31, 2012 and 2011, we had loans payable to QIAGEN Finance of \$145.0 million and accrued interest due to QIAGEN Finance of \$4.4 million. We also had amounts receivable from QIAGEN Finance of \$3.4 million. As of December 31, 2012 and 2011, we have a loan payable to Euro Finance of \$300.0 million, accrued interest due to Euro Finance of \$2.6 million and \$3.0 million, respectively, and amounts receivable from Euro Finance of \$1.3 million and \$1.6 million, respectively. The amounts receivable are related to subscription rights which are recorded net in the equity of QIAGEN N.V. as paid-in capital.

In 2011, we had a consulting agreement with Dr. Metin Colpan, our former Chief Executive Officer and current Supervisory Board member, pursuant to which Dr. Colpan is paid a fee of EUR 2,750 per day for consulting services, subject to adjustment. We incurred consulting expenses of approximately \$0.1 million as of December 31, 2011 for scientific consulting services under this agreement. In January 2012, the agreement under which Dr. Colpan provided scientific consulting services terminated.

During 2012 we entered into a development and license agreement with a company in which we also hold an interest. Under the terms of this agreement we will pay a total of \$7.7 million in 2013 and another \$2.0 million in total based on the achievement of certain milestones.

From time to time, we have transactions with other companies in which we hold an interest, all of which are individually and in the aggregate immaterial, as summarized in the table below.

Years ending December 31 \$ 1,000	2012	2011
Net sales	7,068	6,287
Accounts receivable	2,651	3,606
Accounts payable	3,699	4,642
Accounts receivable	1,674	1,539

## 24. Subsequent Event

Since December 31, 2012, and through February 22, 2013, we have repurchased 1.9 million shares of common shares under the share repurchase program discussed more fully in Note 18, for approximately \$38.5 million, in total.

### List of Subsidiaries

The following is a list of subsidiaries as of December 31, 2011, other than certain subsidiaries that did not in the aggregate constitute a significant subsidiary:

Company Name	Jurisdiction of Incorporation
Cellectis Limited	Australia
Cellectis GmbH	Germany
Corbett Research Ltd Pty	Australia
Ipsogen SA	France
QIAGEN Australia Holding	Australia
QIAGEN Inc. (Canada)	Canada
QIAGEN Deutschland Holding GmbH	Germany
QIAGEN Gaithersburg, Inc.	Delaware
QIAGEN GmbH	Germany
QIAGEN Hamburg GmbH	Germany
QIAGEN, U.S. Finance Holdings	Luxembourg
QIAGEN, Finance (MALTA) Ltd	Malta
QIAGEN, Inc. (USA)	California
QIAGEN Instruments AG	Switzerland
QIAGEN K.K.	Japan
QIAGEN Lake Constance GmbH	Germany
QIAGEN Ltd.	U.K.
QIAGEN Manchester Ltd.	U.K.
QIAGEN Mexico	Mexico
QIAGEN North American Holdings Inc.	California
QIAGEN Pty. Ltd.	Australia
QIAGEN SA	France
QIAGEN Sciences, LLC	Maryland
QIAGEN Shenzhen Co. Ltd.	China
QIAGEN SpA	Italy
Quanta Biosciences, Inc.	Maryland
SABiosciences	Maryland

## Report of Independent Registered Public Accounting Firm

The Supervisory Board and Shareholders of QIAGEN N.V. and Subsidiaries

We have audited the accompanying consolidated balance sheets of QIAGEN N.V. and Subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 18(A). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of QIAGEN N.V. and Subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), QIAGEN N.V. and Subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2013 expressed an unqualified opinion thereon.

**Ernst & Young GmbH**

Wirtschaftsprüfungsgesellschaft  
March 1, 2013  
Düsseldorf, Germany

/s/ Hendrik Hollweg  
Wirtschaftsprüfer  
[German Public Auditor]

/s/ Tobias Schlebusch  
Wirtschaftsprüfer  
[German Public Auditor]

## Report of Independent Registered Public Accounting Firm

The Supervisory Board and Shareholders of QIAGEN N.V. and Subsidiaries

We have audited QIAGEN N.V. and Subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). QIAGEN N.V. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, QIAGEN N.V. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of QIAGEN N.V. and Subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of

income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2012 of QIAGEN N.V. and Subsidiaries and our report dated March 1, 2013 expressed an unqualified opinion thereon.

**Ernst & Young GmbH**

Wirtschaftsprüfungsgesellschaft

March 1, 2013

Düsseldorf, Germany

/s/ Hendrik Hollweg

Wirtschaftsprüfer

[German Public Auditor]

/s/ Tobias Schlebusch

Wirtschaftsprüfer

[German Public Auditor]

# QIAGEN KEY FIGURES

## QIAGEN Key Figures

	2012	2011	2010	2009
<b>\$ 1,000 except per share data</b>				
<b>Results</b>				
Net sales	1,254,456	1,169,747	1,087,431	1,009,825
Operating income	169,814	99,588	188,537	180,205
Net income*	129,506	96,038	144,311	137,767
Basic earnings per share*	0.55	0.41	0.62	0.67
Diluted earnings per share (EPS)*	0.54	0.40	0.60	0.64
<b>Research and Development</b>				
R&D expenses \$ million	122.5	130.6	126.0	107.9
R&D expenses as % of net sales	10	11	12	11
R&D employees	670	758	740	698
<b>Number of shares (in thousands)</b>				
Weighted average number of common shares used to compute basic net income per common share	235,582	233,850	232,635	206,928
Weighted average number of common shares used to compute diluted net income per common share	240,746	239,064	240,483	213,612
<b>Cash flow</b>				
Cash flow from operations	244,880	244,779	250,752	216,995
Capital expenditures for property, plant and equipment	101,996	86,805	79,666	52,179
Free cash flow (Cash flow from operations less capital expenditures)	142,884	157,974	171,085	164,816
Cash EPS (Cash flow from operations / weighted average number of diluted shares)	1.02	1.02	1.04	1.02
<b>Balance sheet</b>				
Total assets	4,087,631	3,729,685	3,878,478	3,769,219
Cash and cash equivalents	394,037	221,133	828,407	825,557
Total long-term liabilities, including current portion	1,101,550	725,874	1,118,932	1,171,065
<b>Total equity*</b>	<b>2,724,363</b>	<b>2,557,798</b>	<b>2,476,353</b>	<b>2,291,169</b>

\* Attributable to the owners of QIAGEN N.V.

<b>As of December 31</b>					
<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
892,975	649,774	465,778	398,395	380,629	351,404
145,662	83,133	100,601	94,837	84,140	68,889
89,033	50,122	70,539	62,225	48,705	42,850
0.45	0.30	0.47	0.42	0.33	0.29
0.44	0.28	0.46	0.41	0.33	0.29
97.3	64.9	41.6	35.8	34.4	31.8
11	10	9	9	9	9
529	461	332	321	276	269
196,804	168,457	149,504	147,837	146,658	145,832
204,259	175,959	153,517	150,172	148,519	147,173
172,998	84,811	101,479	91,237	53,798	64,060
39,448	34,492	28,995	13,728	12,621	19,558
133,550	50,319	72,484	77,509	41,177	44,502
0.85	0.48	0.66	0.61	0.36	0.44
2,810,789	2,775,174	1,212,012	765,298	714,599	551,930
333,313	347,320	430,357	191,700	196,375	98,993
1,128,301	1,220,084	536,738	230,086	234,138	131,095
<b>1,453,844</b>	<b>1,391,575</b>	<b>566,165</b>	<b>450,457</b>	<b>400,376</b>	<b>334,786</b>

# GLOSSARY

## A

**Amplification** Making multiple copies of nucleic acid sequences to enable analysis for diagnostic or identification purposes. Various technologies are used to amplify genomic information in the laboratory, the most popular being the Polymerase Chain Reaction (PCR).

**Applied Testing** Use of Sample & Assay Technologies for professional applications beyond healthcare and research, including human identification and forensics, veterinary testing, food safety and other uses in non-human health applications.

**Assay** Analysis to determine the presence, absence, or quantity of one or more components; a test used in this analysis.

**Autoimmune disease** An illness that occurs when the body tissues are attacked by its own immune system.

## B

**Bacillus Calmette-Guérin (BCG)** A vaccine against tuberculosis.

**Bioinformatics** Software tools to generate useful biological knowledge and store, retrieve, organize and analyze biological data.

**Biomarker** Molecules found in the body that indicate a specific biological condition such as a disease, predisposition to a disease, or response to drugs, which are increasingly used to personalize medical treatments for various conditions.

**Biomedical research** Scientific investigation of any matter related to living or biological systems. "Biomedical" usually denotes an emphasis on problems related to human health and diseases.

**BRAF** A human gene that makes a protein called B-Raf. The B-Raf protein is involved in sending signals inside cells, which are involved in directing cell growth. It's been shown to be faulty (mutated) in human cancers.

## C

**Campylobacter (meaning 'twisted bacteria')** A genus of bacteria that are Gram-negative, spiral, and microaerophilic. The organisms have a characteristic spiral / corkscrew appearance. *Campylobacter jejuni* is now recognized as one of the main causes of bacterial foodborne disease in many developed countries.

**CE mark** A mandatory mark, officially called "CE marking," that designates products as meeting safety, health and environmental requirements for the European Economic Area (EEA). The CE mark is a precondition to market products that can be used for in vitro diagnostics in Europe, and is also accepted by many other countries outside of Europe.

**Clinical trial** A research study involving patients or human subjects. The most common clinical trials evaluate new drugs, medical devices, biologics, or other patient interventions in scientifically controlled settings, and are required for regulatory approval of new therapies or diagnostics.

**Companion diagnostics** A key tool for personalized medicine. Companion diagnostics are tests administered ahead of, or in combination with, individual drug therapies, allowing physicians to assess the likely outcome and safety, and eliminating a "trial and error" approach to treatment of disease.

**Consumables** Kits that contain proprietary sample-processing devices and the chemicals and technical protocols needed to prepare a specified number of samples. QIAGEN consumable products include kits for DNA and RNA separation, purification, stabilization, amplification and analysis, and protein purification – all common steps in research and diagnostic lab settings.

**CT** *Chlamydia trachomatis*, a disease-causing bacteria. Chlamydia infections are the most common bacterial sexually transmitted infections in humans and are the leading cause of infectious blindness worldwide.

**CT scan** Computerized tomography scan.

**Cytology** Study of cells and their structure, function, multiplication and pathology.

**Cytomegalovirus infection (CMV)** A member of the herpes virus group, which also includes herpes simplex virus, varicella-zoster virus (which causes chickenpox) and Epstein-Barr virus (which causes infectious mononucleosis). These viruses share a characteristic ability to remain dormant within the body over a long period.

## D

**DNA** Deoxyribonucleic acid is a molecule seen as a basic building block of life. It contains genetic information including the instructions needed for an organism to develop, survive and reproduce. In DNA, two strands form a double helix structure built up from the four nucleotides, or "bases," adenine, cytosine, guanine and thymine (A, C, G, and T).

**DNA methylation** A type of chemical modification, where DNA acts as an "on" and "off" switch for individual genes. Methylation patterns can be analyzed to diagnose conditions and determine the presence or absence of disease.

**DNA sequencing** The process used to obtain the sequential DNA arrangement of the nucleotides, or “bases,” A, C, G and T. The DNA sequence carries information that a cell needs to assemble protein and RNA molecules and is important in investigating the functions of genes.

**Drug metabolism** The chemical alteration of a drug by the body.

**Drug target** The biological target for a medicine to act in the body and fight disease.

## E

**Epstein-Barr virus (EBV)** A virus of the herpes family, and one of the most common viruses in humans. It is best known as the cause of infectious mononucleosis. It is also called human herpesvirus 4 (HHV-4).

**EGFR** Epidermal growth factor receptor is the cell-surface receptor for members of the epidermal growth factor family of extracellular protein ligands. Mutations involving EGFR could lead to its constant activation, which could result in uncontrolled cell division – a predisposition for cancer. Consequently, mutations of EGFR have been identified in several types of cancer, and it is the target of an expanding class of anticancer therapies.

**Enzyme-linked immunosorbent assay (ELISA)** A test that uses antibodies and color change to identify a substance.

**Epigenetics** A research area devoted to the analysis of hereditary factors that may have an impact on the phenotype of an organism or its gene expression, but are not associated with changes in the underlying DNA sequence. A key mechanism in epigenetics is DNA methylation.

## F

**FDA** The Food and Drug Administration is an agency of the U.S. Department of Health and Human Services responsible for regulating drugs, medical devices, biologicals such as vaccines, food, dietary supplements, blood products, radiation-emitting devices, veterinary products and cosmetics in the United States.

**Forensics** Application of scientific techniques to legal matters – for example, analysis of physical evidence from crime scenes or use of DNA evidence for identification of victims or perpetrators.

**Functional genomics** Study of genes, their resulting proteins and the functions of specific proteins in the body.

## G

**GC** Gonococcus, or Neisseria gonorrhoea, is a species of Gram-negative bacteria responsible for the sexually transmitted disease gonorrhea.

**Gene expression** Transfer of genetic information to its active form, usually from DNA via RNA (transcription) into proteins (translation).

**Gene sequencing** Determining the order of DNA nucleotides or bases in a gene.

**Gene silencing** Repression of gene expression, especially using the recently discovered mechanism of RNAi (RNA interference). siRNA duplexes can be designed to target and repress expression of specific genes.

**Genetic modification (GM)** The process of manipulating genes, usually outside the organism’s normal reproductive process, to obtain different characteristics, for example in genetically modified foods.

**Genome** The entire genetic information of an organism. In most organisms it consists of DNA; in some viruses it can consist of RNA.

**Genomic DNA** A representative sample of DNA contained in a genome.

**Genomics** Scientific study of genes and their role in an organism’s structure, growth, health, disease, ability to resist disease, etc.

**Genotyping** Genetic fingerprinting, DNA testing, DNA typing, and DNA profiling – study or testing of variations in the genetic information among different individuals.

**GMO** Genetically-modified organisms.

## H

**HDA** Helicase-dependent amplification is an amplification technology for nucleic acids working at constant temperatures, unlike changing temperatures involved in PCR.

**Hepatitis B** An infectious inflammatory illness of the liver caused by the hepatitis B virus (HBV).

**Hepatitis C** An infectious disease affecting primarily the liver, caused by the hepatitis C virus (HCV).

**High-throughput screening** Testing of large numbers of samples, often simultaneously.

**Histopathology** The microscopic examination of tissue in order to study the manifestations of disease.

**HIV** The virus that causes acquired immune deficiency syndrome (AIDS); it replicates in and kills the helper T cells.

**HLA** Human leukocyte antigen is a gene product of the major histocompatibility complex that influences immune response. These antigens play an important role in human organ transplantation, transfusions in refractory patients and certain disease associations.

**HPV** A virus identified as a necessary factor in the development of nearly all cases of cervical cancer in women. Approximately 130 human papillomavirus (HPV) types have been identified. Persistent infection with one of 15 "high-risk" subtypes of sexually transmitted HPV may lead to potentially precancerous lesions and can progress to invasive cancer.

**Hybrid capture technology** Proprietary technology used to detect various infections such as HPV, chlamydia trachomatis (CT), Neisseria gonorrhoea (GC) and cytomegalovirus (CMV). In "hybrid capture," RNA probes bind to DNA in the targeted virus or bacterium, forming a "hybrid." This hybrid is then "captured" by an antibody added to the solution. In a later step, additional antibodies that produce light in the presence of hybrids are introduced. They bind to the hybrids, resulting in the emission of light that is measured by an instrument called a luminometer. The amount of light detected indicates the amount of target DNA present.

## I

**Immunoassay** Biochemical test that measures concentration of a specific antibody in a biological liquid, typically serum or urine, using the reaction of an antibody or antibodies to its antigen. The assay takes advantage of the specific binding of an antibody to its antigen.

**Infectious disease** Any disease caused by the entrance, growth, and multiplication of microorganisms in the body; a germ disease.

**In vitro diagnostics** These tests, known as IVD, are medical devices intended to perform diagnoses from assays in a laboratory test tube, or more generally in a controlled environment outside a living organism. In Latin, *in vitro* means "in glass."

## J

**Janus kinase 2 (JAK2)** A gene that provides instructions for making a protein that promotes the growth and division (proliferation) of cells. This protein is part of a signaling pathway called the JAK / STAT pathway, which transmits chemical signals from outside the cell to the cell's nucleus.

## K

**KRAS** The KRAS gene (short for Kirsten rat sarcoma viral oncogene homolog) encodes a protein also known as KRAS that is involved in regulating cell division. While the protein product of the unmutated KRAS gene performs an essential function in normal tissue signaling, mutated KRAS genes are potent oncogenes that play a role in many cancers.

## L

**Laboratory developed tests** In vitro diagnostic tests that are developed, validated and used for in-house pathology and diagnostic purposes. LDTs are intended for use only by the laboratory entity where they are developed, unlike the majority of commercially marketed laboratory tests which are manufactured by medical device companies and sold to laboratories, hospitals or physicians' offices, and must be cleared or approved by the Food and Drug Administration.

**Latent tuberculosis** A patient is infected with Mycobacterium tuberculosis, but does not have active tuberculosis disease. The main risk is that approximately 10 % of these patients will go on to develop active tuberculosis at a later stage of their life.

**Listeria** A type of bacterium (*Listeria monocytogenes*) that infects humans and other warm-blooded animals through contaminated food.

## M

**Metabolic enzyme** A protein that catalyzes biochemical reactions for the synthesis, modification and breakdown of molecules (e.g. drugs) in a living organism. The metabolic enzyme pattern differs within individuals and provides a basis for analyzing individual drug responses in patients.

**Metabolic markers** A molecular marker associated with a metabolic function.

**MicroRNAs (miRNAs)** Single-stranded RNA molecules of about 21–23 nucleotides in length, which regulate gene expression. miRNAs are encoded by genes that are transcribed from DNA but not translated into proteins (non-coding RNA).

**Molecular biology** The study of life processes at the molecular level, typically through the study of nucleic acids (DNA and RNA) and proteins.

**Molecular diagnostics** The use of DNA, RNA and proteins to test for specific health conditions in humans.

**MRI** Magnetic resonance imaging is a medical imaging technique used in radiology to visualize internal structures of the body in detail.

**Multiplex assay** A type of laboratory procedure that performs multiple assays concurrently.

## N

**Next-Generation Sequencing (NGS)** The process of determining the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used

to determine the order of the four bases – adenine, guanine, cytosine, and thymine – in a strand of DNA. The advent of NGS has greatly accelerated biological and medical research and discovery.

**Noroviruses** A group of related, single-stranded RNA (ribonucleic acid) viruses that cause acute gastroenteritis in humans.

**Nucleic acid** Single or double-stranded polynucleotides involving RNA or DNA, which are the crucial building blocks of life involved in the storage and expression of genetic information.

## O

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**Oncogene** An oncogene is a gene that, when mutated or expressed at high levels, helps turn a normal cell into a tumor cell. Examples are PI3K, BRAF, KRAS, BCL-ABL.

**Optical fluorescence detection technology** A technique using optical measurement to quantify and analyze light emissions specific to molecular interactions in a variety of diagnostic and other applications.

## P

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**Pap smear** The Papanicolaou test (also called Pap smear, Pap test, cervical smear, or smear test) is a cytology-based screening test used to detect premalignant and malignant (cancerous) processes in the cervix.

**Pathogen** A pathogen or infectious agent is a biological agent that causes disease or illness.

**Pathway** A series of metabolic / biological actions among molecules in a cell. An understanding of entire pathways and the complex interactions of all molecules involved – as opposed to the study of individual molecules – is a key to understand-

ing the specifics of many diseases and the development of new diagnostics and drugs.

**PCR** Polymerase chain reaction is the most widely used laboratory technique to amplify DNA or RNA sequences. The temperature of a sample is repeatedly raised and lowered to help heat-stable polymerase enzymes copy the target nucleic acid sequence. PCR can produce a billion copies of the target sequence in a few hours.

**Personalized medicine** Use of information from a patient's genotype, level of gene expression and other clinical data to stratify disease, select a medication or dosage, or initiate a therapeutic or preventive measure that is particularly suited to that patient at the time of administration.

**Pharmacogenetics** Study of the association between specific genetic characteristics and response to drug therapy to select "the right medicine for the right patient."

**Pharmacogenomics** Analyzing the entire spectrum of genes that determine drug behavior and sensitivity, pharmacogenomics is concerned with genetic effects on drugs themselves, and with genetic variations that contribute to variable effects of drugs in different individuals.

**Polymerases** Enzymes that catalyze the production of a nucleic acid strand using an existing strand as a template – used in PCR and RT-PCR.

**Predisposition** A genetic effect that influences the observable characteristics of an organism but can be modified by environmental conditions. Genetic testing can identify individuals who are genetically predisposed to certain health problems.

**Primer** A strand of nucleic acid that serves as a starting point for DNA or RNA synthesis. They are required because the enzymes that catalyze replication, DNA polymerases, can only add new nucleotides to an existing strand of DNA.

**Pyrosequencing** A next-generation DNA sequencing technology based on the "sequencing by synthesis" principle. Pyrosequencing enables decoding of short to medium-length DNA sequences and is highly useful for analyzing DNA methylation patterns.

## R

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**Reagent** A chemical substance (other than the specimen) used in conducting a diagnostic test / assay.

**Real-time PCR** Polymerase chain reaction in real time that involves the sequence-specific amplification of DNA molecules using heat-stable polymerase enzymes. It is often used to measure the amount of a specific DNA molecule in a sample.

**Reverse transcription** The process of making a double stranded DNA molecule from a single stranded RNA template through the enzyme, reverse transcriptase.

**RNA** Ribonucleic acid is one of the building blocks of life, included in many types of biologically relevant molecules, especially mRNA (messenger RNA), which is copied from DNA and encodes proteins.

**RNAi** RNA interference is one methodology used to cause gene silencing.

**RT-PCR** Reverse-transcriptase polymerase chain reaction is a technique that transcribes RNA molecules into DNA molecules, which are then amplified by PCR.

## S

**SARS** Severe acute respiratory syndrome is an atypical pneumonia, caused by the SARS coronavirus (SARS CoV), a novel coronavirus.

**Sensitivity** A statistical measure of how well a test correctly identifies a condition. For example, with a medical test to determine if a person has a certain disease, the sensitivity is the probability that if the person has the disease, the test result will be "positive." High sensitivity is required when early diagnosis and treatment are beneficial to patients, or when a disease is infectious and screening is useful to containing it.

**siRNA** Short interfering RNA is a specific short sequence of double-stranded RNA (dsRNA) with less than 30 base pairs.

**SNP** Single nucleotide polymorphism – DNA sequence variations occurring when a single nucleotide (A, T, C or G) in the genome differs between members of a species. Variations in DNA sequences can affect how humans develop diseases and respond to pathogens, drugs, vaccines and other agents, and thus serve as potential biomarkers. SNPs are thought to be key enablers in achieving the potential of personalized medicine.

**Specificity** A statistical measure of how well a test correctly identifies the negative cases, those that do not meet the condition under study. For example, specificity in a medical test to determine if a person has a certain disease is the probability that a "negative" result accurately indicates that the person does not have the disease. High specificity is important when the treatment or diagnosis could be harmful to patients mentally and/or physically.

**Swine flu** Any strain of the influenza virus that can be endemic in pigs (swine), and also found in humans. The 2009–2010 pandemic in humans, widely known as "swine flu" or "H1N1," was due to a strain of influenza. A virus subtype H1N1 that global health authorities viewed as a particularly dangerous threat.

## T

**Test kit** An FDA cleared or approved test package that includes all of the reagents necessary to obtain test results and a protocol with instructions for using the test kit.

**Translational medicine** The findings in basic research are more quickly and efficiently translated into medical practice and resulting in faster and better outcomes for patients.

**Trichella** The genus of parasitic roundworms of the phylum Nematoda that cause trichinosis.

## W

**Workflow** An orderly series of steps a laboratory must follow to take a sample from raw biological material through isolation and purification, identification and measurement by molecular assays, on to analysis and through final results. Automation systems increasingly move beyond individual lab tasks to focus on enhancing the efficiency of entire workflows.

## Z

**Zoonosis** A disease that normally exists in animals but that can infect humans. There are multitudes of zoonotic diseases.



# SERVICE

## Corporate Communications

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## Sources

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## Financial Calendar

### APRIL 29, 2013

First Quarter 2013 Results

### JUNE 26, 2013

Annual General Meeting

### JULY 30, 2013

Second Quarter 2013 Results

### OCTOBER 29, 2013

Third Quarter 2013 Results

### JANUARY 2014

Fourth Quarter 2013 Results

## Credits

### CONCEPT AND DESIGN

3st kommunikation, Mainz

### PHOTOGRAPHY

All photos by Andreas Fechner except pages 14, 84 (Michael Dannenmann), page 18 (Rüdiger Nehmzow), page 85 (M. Dannenmann, R. Nehmzow), 4, 5, 60-61, 76-77 (Getty Images), and pages 38, 80 (private photos)

## Publication Date

Our annual report of record is the Form 20-F filed with the U.S. Securities and Exchange Commission on February 22, 2013. This annual report, which includes key elements of the Form 20-F filing, was published in March 2013.

## Trademarks

Our name together with our logo is registered as a trademark in the United States and a number of other countries: QIAGEN®.

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In this annual report QIAGEN is using the term molecular diagnostics. The use of this term is in reference to certain countries, such as the United States, limited to products subject to regulatory requirements. As of February 2013, QIAGEN molecular diagnostics products included 12 FDA (PMA approved or 510K cleared) products, 17 clinical sample concentrator products (13 kits and 4 instruments), 74 EU CE IVD assays, 9 EU CE IVD sample preparation products, 21 EU CE IVD instruments for sample purification or detection, 11 China SFDA IVD assays and 10 China SFDA IVD instruments.

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# HIGHLIGHTS 2012

Progress on Strategic Initiatives drives Innovation and Growth



Drive platform success  
Grow installed  
instrument base



Add content  
Offer new tests across  
all customer classes

## QIAsymphony

- More than 750 installed systems worldwide
- Double-digit sales growth in consumables
- Strong demand in all geographic regions

## Next-generation sequencing

- Development of sample-to-result workflow solution underway
- Targeting applications in clinical research and healthcare

## QIAensemble

- Successful launch of QIAensemble Decapper to further improve HPV test automation

## Test portfolio

- 35 assays in Molecular Diagnostics development pipeline
- Successful launch of first universal products for NGS applications
- Acquisition of AmniSure ROM test
- Rights to novel biomarkers for TNF-alpha blockers, lung and colon cancer

## Selected regulatory approvals

- *therascreen KRAS* (U.S.)
- *artus Influenza* (U.S.)
- *therascreen BRAF* (EU)
- *careHPV* (China)

## Selected regulatory submissions

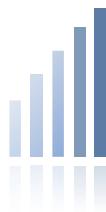
- *therascreen EGFR* (U.S.)
- *QuantiFERON CMV* (U.S.)

## Development partnerships

- New co-development agreements for companion diagnostics with leading pharmaceutical companies



Broaden geographic presence  
Expand into attractive markets



Grow efficiently and effectively  
Grow with best-in-class teams

#### Growth

- Dynamic growth in Top 7 emerging growth markets China, Brasil, India, Mexico, Russia, South Korea, Turkey

#### Expansion

- Collaboration agreements with local partners expand access to QIAGEN technologies in China
- New subsidiary in Poland

#### Structure and leadership

- Creation of two business areas, Molecular Diagnostics and Life Sciences
- Transforming senior leadership team with new appointments

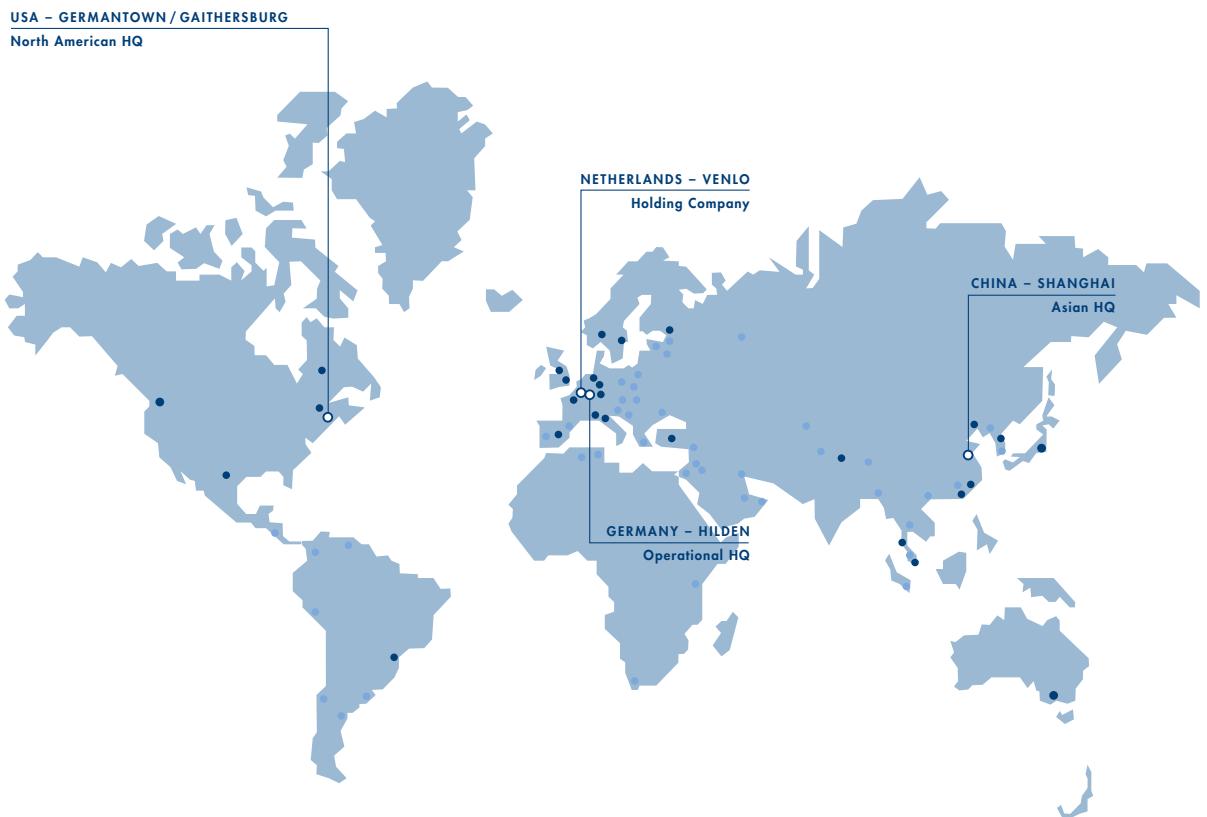
#### Efficient growth

- Exceeded sales and adjusted earnings targets

#### Shareholder value

- Initiated \$100 million share repurchase program

# QIAGEN AROUND THE WORLD



○ Headquarters   ● QIAGEN Companies   ● QIAGEN Distributors and Importers

For a full list of our subsidiaries and distributors, please visit [www.qiagen.com/contact/](http://www.qiagen.com/contact/)

