QIAGEN NV
Form 20-F
February 29, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 20-F

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

or

S ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2015

or

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

or

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

Commission File Number 0-28564

QIAGEN N.V.
(Exact name of Registrant as specified in its charter)
n/a
(Translation of Registrant's name in English)
The Netherlands
(Jurisdiction of incorporation or organization)
Hulsterweg 82
5912 PL Venlo
The Netherlands
011-31-77-355-6600
(Address of principal executive offices)

Roland Sackers, Tel: 011-31-77-355-6600, Fax: 011-31-77-355-6658
QIAGEN N.V., Hulsterweg 82, 5912 PL Venlo, The Netherlands
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class:	Name of each exchange on which registered:
Common Shares, par value EUR 0.01 per share	NASDAQ Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act:
None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None

The number of outstanding Common Shares as of December 31, 2015 was 233,005,776.
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ý Yes o No

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

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ý Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ý Yes o No

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

Large accelerated filer ý Accelerated filer o Non-accelerated filer o

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

ý U.S. GAAP

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

o Other

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

o Item 17

o Item 18

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

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

EXCHANGE RATES

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

The exchange rate used for the euro was obtained from the European Central Bank and is based on a regular daily concentration procedure between central banks across Europe and worldwide, which normally takes place at 2:15 P.M. Central European Time. This rate at February 24, 2016, was $1.0981 per €1.

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

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PART I

Item 1. Identity of Directors, Senior Management and Advisors
Not applicable.

Item 2. Offer Statistics and Expected Timetable
Not applicable.

Item 3. Key Information
QIAGEN N.V. is registered under its commercial and legal name 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.
The selected consolidated financial data below should be read in conjunction with “Operating and Financial Review and Prospects” and the Consolidated Financial Statements, including the notes and other financial information included in this Annual Report on Form 20-F. The selected financial data below is derived from the consolidated statements of income for the years ended December 31, 2015, 2014 and 2013 and the consolidated balance sheets at December 31, 2015 and 2014 of QIAGEN that have been audited by an independent registered public accounting firm, and are included in this Annual Report. The selected data from the consolidated statements of income presented for the years ended December 31, 2012 and 2011, and the consolidated balance sheets as of December 31, 2013, 2012 and 2011, is derived from audited consolidated financial statements not included in this Annual Report. The 2011 amounts for working capital, total assets and total long-term liabilities, including current portion, have been adjusted to correctly reflect deferred taxes as current or non-current and to net deferred tax positions within the same tax jurisdictions. These balance sheet reclassifications had no effect on total equity at December 31, 2011.

Selected Financial Data

The information below should be read in conjunction with the Consolidated Financial Statements (and accompanying notes) and "Operating and Financial Review and Prospects."

	Years ended December 31,				
	2015	2014	2013	2012	2011
Consolidated Statement of Income Data: (amounts in thousands, except per share data)					
Net sales	$1,280,986	$1,344,777	$1,301,984	$1,254,456	$1,169,747
Cost of sales	454,611	479,839	486,494	430,432	419,938
Gross profit	826,375	864,938	815,490	824,024	749,809
Operating expenses:					
Research and development	147,180	163,627	146,070	122,476	130,636
Sales and marketing	360,962	376,873	371,523	343,549	307,332
General and administrative, restructuring, integration and other	103,874	126,550	199,072	152,068	185,507
Acquisition-related intangible amortization	38,666	37,070	35,495	36,117	26,746
Total operating expenses	650,682	704,120	752,160	654,210	650,221
Income from operations	175,693	160,818	63,330	169,814	99,588
Other expense	(43,195)	(42,304)	(25,992)	(24,661)	(3,376)
Income before income taxes	132,498	118,514	37,338	145,153	96,212
Income taxes	5,641	1,312	(31,760)	15,616	1,263
Net income	$126,857	$117,202	$69,098	$129,537	$94,949
Net (loss) income attributable to noncontrolling interest	(246)	568	25	31	(1,089)
Net income attributable to QIAGEN N.V.	$127,103	$116,634	$69,073	$129,506	$96,038
Basic net income per common share attributable to the owners of QIAGEN N.V. [1]	$0.54	$0.50	$0.30	$0.55	$0.41
Diluted net income per common share attributable to the owners of QIAGEN N.V. [1]	$0.54	$0.48	$0.29	$0.54	$0.40
Weighted-average common shares outstanding					
Basic	233,483	232,644	234,000	235,582	233,850
Diluted	237,158	241,538	242,175	240,746	239,064

(1) See Note 18 of the “Notes to Consolidated Financial Statements” for the computation of the weighted average number of Common Shares.

	As of December 31,				
	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data: (amounts in thousands)					
Cash and cash equivalents	$290,011	$392,667	$330,303	$394,037	$221,133
Working capital [1]	$693,261	$717,124	$583,851	$725,752	$293,753
Total assets	$4,189,678	$4,454,372	$4,088,392	$4,087,631	$3,729,685
Total long-term liabilities, including current portion	$1,360,293	$1,496,991	$1,032,409	$1,101,550	$725,874
Total equity	$2,561,954	$2,657,999	$2,723,871	$2,724,363	$2,557,798
Common shares, par value	$2,812	$2,812	$2,812	$2,769	$2,739
Common shares issued	239,707	239,707	239,707	236,487	234,221
Common shares outstanding	233,006	232,023	233,890	234,544	234,221

(1) Working capital is current assets less current liabilities.

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Risk Factors

Risk Management:

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

QIAGEN 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 risk management system. The Managing Board has developed and implemented strategies, controls and mitigation measures to identify current and developing risks as part of the 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 and that threatens our current and existing business;
- A business growth risk is specific to us or our industry that threatens our future business growth; and
- An underlying business risk is not specific to us or our industry, but applies 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 implement mitigation actions. The results of the risk assessment, and any updates, are reported to the Audit Committee of the Supervisory Board on a regular basis. A detailed risk reporting update is provided each quarter to the Audit Committee for specific risks that have been newly identified or have changed since the previous assessment. A detailed review of all underlying business risks is completed every year. At least once on an annual basis, 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 of 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 that outlines the responsibilities of our Managing and Supervisory Boards (discussed in more detail in Item 10 of this Annual Report) and the function of the Audit Committee of the Supervisory Board (discussed in more detail in Item 6 of this Annual Report). We maintain adequate internal controls over financial reporting to ensure the integrity of financial reporting, which is described further in Item 15 of this Annual Report. Additionally, a Compliance Committee operates under the leadership of the Chief Financial Officer, who is also a member of the Managing Board, that consists of senior executives from various functional areas who are responsible for ensuring compliance with legal and regulatory requirements, as well as overseeing the communication of corporate policies, including our Code of Ethics as described further in Item 16B of this Annual Report.

Risk Types	
Base Business Risk	• Identification and monitoring of competitive business threats • Monitoring complexity of product portfolio • Monitoring dependence on key customers for single product groups • Reviewing dependence on individual production sites or suppliers • Evaluating purchasing initiatives, price controls and changes to reimbursements • Monitoring 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 • Evaluating financial risks, including economic risks and currency rate fluctuations • Monitoring financial reporting risks, including multi-jurisdiction tax compliance
Underlying Business Risk	• Reviewing possible asset impairment events • Assessing compliance and legal risks, including safety in operations and environmental hazard risks, compliance with various regulatory bodies and pending product approvals • Monitoring risks of FCPA (Foreign Corrupt Practices Act) or antitrust concerns arising from a network of subsidiaries and distributors in foreign countries

The risks described below are listed in the order of our current view of their expected significance. Describing the risk factors in order of significance does not imply that a lower listed risk factor may not have a material adverse impact on our results of operations, liquidity or capital resources.

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, with total net sales increasing to $1.28 billion in 2015 from $1.17 billion in 2011. We have made a series of acquisitions in recent years, including MO BIO Laboratories in 2015, Enzymatics and BIOBASE in 2014, Ingenuity and CLC bio in 2013, and Intelligent BioSystems and AmniSure in 2012. We intend to identify and acquire other businesses in the future that support our strategy to build on our global leadership position in Sample to Insight solutions. 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. We completed an expansion project in Germany in early 2012 and another at our facility in Germantown, Maryland, for research, production and administrative space in 2013. We completed two smaller-scale building projects in 2015. These expansion projects have increased our fixed costs, resulting in higher operational costs in the short term that will negatively impact our gross profit and operating income until we more fully utilize the additional capacity of these planned facilities. In 2012, we added a subsidiary in Poland as part of the creation of a new global shared services center to gain economies of scale in various administrative functions. We also continue to upgrade our operating and financial systems and expand the geographic presence of our operations, which has resulted in the reallocation of existing resources or the hiring of new employees as well as increased responsibilities for both existing and new management personnel. The

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. Acquisitions expose us to new operating and other risks, including risks associated with the:

- assimilation of new products, technologies, operations, sites and personnel;

- integration and retention of fundamental personnel and technical expertise;
- application for and achievement of regulatory approvals or other clearances;
- diversion of resources from our existing products, business and technologies;
- generation of sales to offset associated acquisition costs;
- implementation and maintenance of uniform standards and effective controls and procedures;
- maintenance of relationships with employees and customers and integration of new management personnel;
- issuance of dilutive equity securities;
- incurrence or assumption of debt;
- amortization or impairment of acquired intangible assets or potential businesses; and
- exposure to liabilities of and claims against acquired entities.

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

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

Rapid technological change and frequent new product introductions are typical in 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. In the past, we have experienced delays in the development and introduction of products, including regulatory approvals, and we may experience delays in the future.

As a result, we cannot assure you that we will keep pace with the rapid rate of change in our markets or that our new products will adequately meet the requirements of the marketplace, achieve market acceptance or regulatory approval or compete successfully with competitive technologies. Some of the factors affecting market acceptance of new products include:

- availability, quality and price relative to competitive products;
- the timing of introduction of the new product relative to competitive products;
- opinions of the new product’s utility;
- citation of the new product in published research;
- regulatory trends and approvals; and
- general trends in life sciences research, applied markets and molecular diagnostics.

In the development of new products we may make significant investments in intellectual property and software. These investments increase our fixed costs, resulting in higher operational costs in the short term that will negatively impact our gross profit and operating income until products reach a minimum level of market acceptance. 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 medium-throughput QIAsymphony automation platform, our new GeneReader NGS System for next-generation sequencing (NGS), sample and assay technologies designed either for QIAGEN instruments or for "universal" use on other platforms, and bioinformatics solutions to analyze and interpret genomic data.

The speed and level of adoption of our QIAsymphony and GeneReader NGS platforms will affect sales not only of instrumentation but also of consumables, sample and assay kits, designed to run on the systems. The rollouts of QIAsymphony and GeneReader NGS System are intended to drive the dissemination and increasing sales of consumables for these systems. We are developing or co-developing new kits for each of these platforms and seeking regulatory approvals for a number of these new products. In turn, the availability and regulatory approval of more tests to run on QIAsymphony or GeneReader NGS System, especially molecular assays for specific diseases or companion diagnostics paired with new drugs, will influence the value of the instruments to prospective buyers. Slower adoption of QIAsymphony, including the complete QIAsymphony RGQ system, or the GeneReader NGS

System could significantly affect sales of products designed to run on these platforms.
Our strategic initiative in NGS, including rollout of the GeneReader NGS System and related consumables, aims to drive the adoption of this technology in clinical research and diagnostics. This involves development and commercialization of universal pre-analytic and bioinformatics products for NGS, as well as commercialization of our proprietary GeneReader NGS workflow

and related consumables. The market for next-generation sequencing instruments is very competitive, and the speed and level of adoption of our universal solutions and the GeneReader workflow will affect sales of our Sample to Insight solutions.

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 financial markets. In times of economic hardship or high unemployment, patients may decide to forgo 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 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 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 any governmental actions or inaction resulting in automatic government spending cuts (sequestration) that may take effect (as in the U.S. 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 U.S. National Institutes of Health (NIH) and similar bodies.

As is the case for many businesses, we face the following risks in regard to financial markets:

- severely limited access to financing over an extended period of time, which may limit our ability to fund our growth strategy and could result in delays to capital expenditures, acquisitions or research and development projects;
- failures of currently solvent financial institutions, which may cause losses from our short-term cash investments or our hedging transactions due to a counterparty's inability to fulfill its payment obligations;
- inability to refinance existing debt at competitive rates, reasonable terms or sufficient amounts; and
- increased volatility or adverse movements in foreign currency exchange rates.

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 or may negatively impact our profitability.

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.

Further, the ability of many of our customers to successfully market their products depends in part on the extent to which reimbursement for the costs of these products is available from governmental health administrations, private health insurers and other organizations. Governmental and other third-party payors are increasingly seeking to contain healthcare costs and to reduce the price of medical products and services. For example, in 2010 the United States enacted major healthcare reform legislation known as the Patient Protection and Affordable Care Act (ACA) which is expected to impact the scope and nature of Medicare reimbursement methods. As a result, the biotechnology, diagnostics and pharmaceutical industries are exposed to the potential risk of price controls by these entities. If there

are not adequate reimbursement levels, our business and results of operations could be adversely affected.

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 22% 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 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.

Competition could reduce our sales.

We face various competitive factors against greater adoption of our products, in particular the use of “home-brew” or lab-developed methods, where widely available reagents and other chemicals are used in a non-standardized manner to perform sample and assay processing. We are also aware that a significant number of laboratory organizations and competitors are developing and using their own internally developed molecular tests. Some competitor companies may seek regulatory approvals from the U.S. Food and Drug Administration (FDA) or similar non-U.S. regulatory authorities and bring to the market alternative products that could limit the use of our products. The success of our business depends in part on the continued conversion of current users of “home brew” methods to our standardized sample and assay technologies and other products. There can be no assurance, however, as to the continued conversion of these potential customers.

We have experienced, and expect to continue to experience, increasing competition from companies that provide competitive pre-analytical solutions and also other products used by our customers. The markets for some of our products are very competitive and price sensitive. Other product suppliers may have significant advantages in terms of financial, operational, sales and marketing resources as well as experience in research and development. These companies may have developed, or could develop in the future, new technologies that compete with our products or even render our products obsolete. The development of products offering superior technology or a more cost-effective alternative to our products could have a material adverse effect on our results of operations.

We believe that customers in the market for pre-analytical sample technologies as well as for assay technologies display significant loyalty to their initial supplier of a particular product, in particular given the time and expense required by customers to properly integrate these products into their operations. As a result, it may be difficult to convert customers who have purchased products from competitors, and our competitive position may suffer if we are unable to be the first to develop and supply new products.

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 regulation 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 diagnostics applications, require regulatory approvals in various countries. For example, since the European Union Directive 98/79/EC on in vitro diagnostic medical devices (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. While this is fully established today, the European Commission and the European parliament have approved a major recast to this directive. While this recast is still in the final stages of the political process called the “Trilogue”, once implemented it will re-classify medical devices, add additional emphasis on clinical efficacy and bring this into a new legal framework. It is anticipated that industry will have at least 5 years to fully implement this after the approval but this is still in negotiation as part of the Trilogue.

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, record-keeping, advertising and promotion. Compliance with these regulations is expensive and time-consuming.

Each medical device that we wish to distribute commercially in the U.S. will likely require us to seek either 510(k) clearance or approval of a pre-market approval application (PMA) from the FDA prior to marketing the device for in-vitro diagnostic use. Clinical trials related to our regulatory submissions take years to complete and represent a significant expense. The 510(k) clearance pathway usually takes from three to 12 months, but can take longer. The PMA pathway is more costly, lengthy and uncertain, and can take from one to three years, or longer. For example, it took more than four years to receive pre-market approval from the FDA for our HPV test product for use as a test for the presence of HPV in women with equivocal Pap test results and pre-market approval for the use of our HPV test as a primary adjunctive cervical cancer screening test to be performed in combination with the Pap test for women age 30 and older. The uncertain time period required for regulatory review increases our costs to develop new products and increases the risk that we will not succeed in introducing or selling new products in the U.S.

Our cleared or approved devices, including our diagnostic tests and related equipment, are subject to numerous post-approval requirements. We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA determines that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from warning letters to more severe sanctions such as fines, injunctions and civil penalties, recalls or seizures of our products, operating restrictions, partial suspension or total shutdown of production, denial of our requests for 510(k) clearance or pre-market approval of product candidates, withdrawal of 510(k) clearance or pre-market approval already granted and criminal prosecution. Any enforcement action by the FDA may affect our ability to commercially distribute these products in the U.S.

Some of our products are sold for research purposes in the U.S. We do not promote these products for clinical diagnostic use, and they are labeled “For Research Use Only” (RUO) or “for molecular biology applications.” If the FDA were to disagree with our designation of a product, we could be forced to stop selling the product until appropriate regulatory clearance or approval has been obtained. Further, some of our products are used in “Laboratory-Developed Tests” (LDTs), where laboratories use our materials for assays manufactured, validated and performed in house. We do not promote these products for clinical diagnostic use.

Further, the FDA has publicly announced its intention to begin regulating lab-developed tests in a phased-in approach, but details of proposed regulations have not yet emerged. LDTs represent the majority of molecular tests currently in

use in terms of volume, and our automation systems - particularly the QIAsymphony platform - are designed to accommodate the automation and validation of these tests. On the other hand, laboratories creating LDTs may use some of our materials in their tests. We do not promote these products for clinical diagnostic use, but if the FDA were to stop the use of LDTs or significantly limit their area of application, sales of some of our products in the U.S. could be adversely affected. The flexibility to handle LDTs is an advantage for our instruments, particularly the QIAsymphony automation system. On the consumables side, however, LDTs can at times create competition to our own commercially approved tests. We are pursuing a strategy of developing new content for our platforms partly by seeking regulatory approvals for new assays that incorporates approvals for these tests to run on QIAGEN instruments. We believe standardized tests that pass regulatory scrutiny and are clinically

validated are highly attractive to reference laboratories and healthcare providers in our Molecular Diagnostics customer class, and also to customers in Pharma and Academia who rely on molecular assays to research and develop new products. At this point the ultimate impact of potential new FDA policies on LDTs is uncertain.

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

Because 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. 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.

Changes in tax laws or their application or the termination or reduction of certain government incentives, could adversely impact our overall effective tax rate, results of operations or financial flexibility.

Our effective tax rate reflects the benefit of some income being partially exempt from income taxes due to various intercompany operating and financing activities. The benefit also derives from our global operations where certain income or loss is taxed at rates higher or lower than The Netherlands' statutory rate of 25%. 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 and limit our ability to repurchase our Common Shares without experiencing adverse tax consequences. Additionally, changes in other laws may subject us to additional excise taxes, such as the U.S. health care reform legislation that was signed into law in the U.S. in 2010. The increased tax burden as a result of changes in law may adversely affect our results of operations. Additionally, if our tax positions are challenged by tax authorities or other governmental bodies, such as the European Commission, we could incur additional tax liabilities, which could have an adverse effect on our results of operations or financial flexibility.

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 to a high degree on the commercial success of the related medicines for which the tests have been designed to be used for determining their use in patients. 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' commercialization actions and 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.

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, the United Kingdom and the U.S. 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.

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 otherwise operate our business. While our global operations give us the ability to ship product 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 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 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 qualified personnel, any of whom we may lose at any time.

Although we have not experienced any difficulties attracting or retaining 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 and managers 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 and retain qualified 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 because it is during this period that they receive new information on both their budgets and requirements. Additionally, volatility in the timing of milestones from companion diagnostic partnerships can be difficult to predict. 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. If we fail to achieve our forecasted sales for a particular quarter, the value of our Common Shares could be adversely affected.

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

We have a significant amount of debt and debt service obligations as well as restrictive covenants imposed on us by our lenders. A high level of indebtedness increases the risk that we may default on our debt obligations and restrictive covenants may prevent us from borrowing additional funds. There is no assurance that we will be able to generate sufficient cash flow to pay the interest on our debt and comply with our debt covenants 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 and comply with our debt covenants, we may have to delay or curtail our research and development programs. The level of our indebtedness could, among other things:

- make it difficult for us to make required payments on our debt;
- make it difficult for us to obtain any financing in the future necessary for working capital, capital expenditures, debt service requirements or other purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- make us more vulnerable in the event of a downturn in our business.

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

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

- marketing, sales and customer support efforts;
- research and development activities;
- expansion of our facilities;
- consummation of possible future acquisitions of technologies, products or businesses;
- demand for our products and services;
- repayment or refinancing of debt; and
- payments in connection with our hedging activities.

We currently anticipate that our short-term capital requirements will be satisfied by cash flow from our operations. As of December 31, 2015, we had outstanding long-term debt of approximately $1.1 billion, of which no amount was current. Furthermore, as of December 31, 2015, we had capital lease obligations, including the current portion, of $3.3 million, that expire in various years through 2018. We may need to refinance all or part of these liabilities before or at their contractual maturities.

We currently do not foresee that this will happen, but if at some point in time our existing resources should be insufficient to fund our activities, we may need to raise funds through public or private debt or equity financings. The funds for the refinancing of existing liabilities or for the ongoing funding of our business may not be available or, if available, not on terms acceptable to us. If adequate funds are not available, we may be required to reduce or delay expenditures for research and development, production, marketing, capital expenditures and/or acquisitions, which could have a material adverse effect on our business and results of operations. To the extent that additional capital is raised through the sale of equity or convertible securities, the issuance of any securities could result in dilution to our shareholders.

The accounting for the Cash Convertible Notes will result in recognition of interest expense significantly greater than the stated interest rate of the notes and may result in volatility to our Consolidated Statements of Income.

We will settle any conversions of the Cash Convertible Notes entirely in cash. Accordingly, the conversion option that is part of the Cash Convertible Notes will be accounted for as a derivative pursuant to accounting standards relating to derivative instruments and hedging activities. Refer to Note 13, “Derivatives and Hedging” and Note 15 "Lines of Credit and Debt," of the Notes to Consolidated Financial Statements. In general, this resulted in an initial valuation of the conversion option separate from the debt component of the Cash Convertible Notes, resulting in an original issue discount. The original issue discount will be accreted to interest expense over the term of the Cash Convertible Notes,

which will result in an effective interest rate reported in our financial statements significantly in excess of the stated coupon rates of the Cash Convertible Notes. This accounting treatment will reduce our earnings. For each financial statement period after the issuance of the Cash Convertible Notes, a gain (or loss) will be reported in our financial statements to the extent the valuation of the conversion option changes from the previous period. The Call Options will also be accounted for as derivative instruments, substantially offsetting the gain

(or loss) associated with changes to the valuation of the conversion option. This may result in increased volatility to our results of operations.

The cash convertible note hedge and warrant transactions we entered into in connection with the issuance of our Cash Convertible Notes may not provide the benefits we anticipate, and may have a dilutive effect on our common stock.

Concurrently with the issuance of the Cash Convertible Notes, we entered into Call Options and issued Warrants. We entered into the Call Options with the expectation that they would offset potential cash payments by us in excess of the principal amount of the Cash Convertible Notes upon conversion of the Cash Convertible Notes. In the event that the hedge counterparties fail to deliver potential cash payments to us, as required under the Call Options, we would not receive the benefit of such transaction. Separately, we also issued Warrants. The Warrants could separately have a dilutive effect to the extent that the market price per share of our common stock, as measured under the terms of the Warrants, exceeds the strike price of the Warrants.

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

At December 31, 2015, our consolidated balance sheet reflected approximately $1.9 billion of goodwill and approximately $636.4 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) requires 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.

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.

Our business involves operations in several countries outside of the U.S. Our consumable manufacturing facilities are located in Germany, China, the United Kingdom and the U.S. 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, South Africa 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.

Unethical behavior and non-compliance with laws by our sales agents, consultants, distributors or employees could seriously harm our business.

Our business in countries with a history of corruption and transactions with foreign governments increase the risks associated with our international activities. Based on our international operations, we are subject to the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act and other laws that prohibit improper payments or offers of payments to foreign governments and their officials and political parties by business entities for the purpose of obtaining or retaining business. We have operations, agreements with third parties and make sales in countries known to experience corruption. Further international expansion may involve increased exposure to such practices. Our activities in these countries, and in all countries as well, create risks of unauthorized payments or offers of payments, non-compliance with laws, or other unethical behavior by any of our employees, consultants, sales agents or distributors, that could be in violation of various laws, including the FCPA, even though these parties are not always subject to our control. It is our policy to implement safeguards to discourage these or other unethical practices by our employees and distributors including online and in-person employee trainings, periodic internal audits and standard reviews of our distributors. However, our existing safeguards and any future improvements may not prove to be effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Violations of the FCPA and other laws may result in criminal or civil sanctions, which could be severe, and we may be subject to other liabilities, which could negatively affect our business, results of operations and financial condition.

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

Our top seven emerging markets are Brazil, Russia, India, China, South Korea, Mexico and Turkey, which together accounted for approximately 15% of total sales in 2015, 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.

We are subject to privacy and data security laws and rely on secure communication and information systems which, in the event of a breach or failure, expose us to risks.

We rely heavily on communications and information systems to conduct our business. In the ordinary course of business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, in our data centers and on our networks. Our operations rely on the secure processing, storage and transmission of confidential and other information on our computer systems and networks. A breach in cyber security due to gaining unauthorized access to our computer systems could include the misappropriation of assets or sensitive information, the corruption data or other operational disruption. Failures to our computer systems and networks could be caused by internal or external events, such as incursions by intruders or hackers, computer viruses, failures in hardware or software, or cyber terrorists. If we do experience a breach or failure of our systems, we could experience operational delays resulting from the disruption of systems, loss due to theft or misappropriation of assets or data, or negative impacts from the loss of confidential data or intellectual property. We may face significant liability in the event any of the personal information we maintain is lost or otherwise subject to misuse or other wrongful use, access or disclosure. Further, we could experience negative publicity resulting in reputation of brand damage with customers or partners.

Additionally, we are subject to privacy and data security laws, including those relating to the storage of health information, which are complex, overlapping and rapidly evolving. As our activities continue to evolve and expand, we may be subject to additional laws which impose further restrictions on the transfer, access, use, and disclosure of health and other personal information which may impact our business either directly or indirectly. Our failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact our

business and future business plans. For example, we may be subject to regulatory action or lawsuits in the event we fail to comply with applicable privacy laws.

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, 2015, we owned 298 issued patents in the United States, 199 issued patents in Germany and 1,234 issued patents in other major industrialized countries. In addition, at December 31, 2015, we had 859 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.

A significant portion of HPV-related intellectual property is in the public domain, while additional HPV-related intellectual property is subject to our patents some of which will begin to expire in the next few years or are licensed to us on a non-exclusive basis. As a result, other companies have developed or may develop HPV detection tests.

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

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

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

We are subject to risks associated with patent litigation.

The biotechnology industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We are aware that patents have been applied for and/or issued to third parties claiming technologies 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 operating results may vary significantly from period to period and this may affect the market price of our Common Shares.

Our operating results may vary significantly from quarter to quarter, and also from year to year, since they are dependent upon a broad range of factors that include demand for our products, the level and timing of customer research budgets and commercialization efforts, the timing of government funding budgets of our customers, the timing of our research and development activities and related regulatory approvals, the impact of sales and marketing expenses, the introduction of new

products by us or our competitors, competitive market conditions, exchange rate fluctuations and general economic conditions. Our expense levels are based in part on our expectations as to future sales trends. As a result, sales and earnings may vary significantly from quarter to quarter or from year to year, and actual sales and earnings results in any one period will not necessarily be indicative of results to be anticipated in subsequent periods. Our results may also fail to meet or exceed the expectations of securities analysts or investors, which could cause a decline in the market price of our Common Shares.

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

QIAGEN N.V. is incorporated under Dutch law as a public limited liability company (naamloze vennootschap), and is organized as a holding company. Currently, the material assets are the outstanding shares of the QIAGEN subsidiaries, intercompany receivables and other financial assets such as cash and short-term investments. As a result, QIAGEN N.V. is dependent upon payments, dividends and distributions from the subsidiaries for funds to pay operating and other expenses as well as to pay future cash dividends or distributions, if any, to holders of our Common Shares. Dividends or distributions by subsidiaries in a currency other than the U.S. dollar may result in a loss upon a subsequent conversion into U.S. dollars.

U.S. civil liabilities may not be enforceable against us.

We are incorporated under Dutch law, and substantial portions of our assets are located outside of the U.S. In addition, certain members of our Managing and Supervisory Boards and our officers reside outside the U.S. As a result, it may be difficult for investors to effect service of process within the U.S. upon us or such other persons, or to enforce outside the U.S. any judgments obtained against such persons in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. securities laws.

In addition, it may be difficult for investors to enforce, in original actions brought in courts in jurisdictions located outside the U.S., rights predicated upon the U.S. securities laws. There is no treaty between the U.S. and the Netherlands for the mutual recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. As a result, a final judgment for the payment of money rendered by any federal or state court in the U.S. based on civil liability, whether or not predicated solely upon the federal securities laws, would not be directly enforceable in the Netherlands. However, if the party in whose favor such final judgment is rendered brings a new suit in a competent court in the Netherlands, such party may submit to the Dutch court the final judgment which has been rendered in the U.S. If the Dutch court finds that the jurisdiction of the federal or state court in the U.S. has been based on grounds that are internationally acceptable and that proper legal procedures have been observed, the Dutch court will, in principle, give binding effect to the final judgment which has been rendered in the U.S. without substantive re-examination or re-litigation on the merits of the subject matter thereof, unless such judgment contravenes Dutch principles of public policy. Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us, members of our Managing or Supervisory Boards, or officers who are residents of the Netherlands or countries other than the U.S. any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the federal securities laws. In addition, there is doubt as to whether a Dutch court would impose civil liability on us, the members of our Managing or Supervisory Boards, or our officers in an original action predicated solely upon the federal securities laws of the U.S. brought in a court of competent jurisdiction in the Netherlands against us or such members or officers, respectively.

Our Common Shares may have a volatile public trading price.

The market price of our Common Shares since our initial public offering in September 1996 has increased significantly and been highly volatile. In the last two years, the price of our Common Shares has ranged from a high of $28.53 to a low of $19.46 on NASDAQ, and a high of €26.05 to a low of €14.38 on the Frankfurt Stock Exchange. In addition to overall stock market fluctuations, factors that may have a significant impact on the price of our Common Shares include:

- announcements of technological innovations or the introduction of new products by us or our competitors;
- developments in our relationships with collaborative partners;
- quarterly variations in our operating results or those of our peer companies;
- changes in government regulations, tax laws or patent laws;
- developments in patent or other intellectual property rights;
- developments in government spending budgets for life sciences-related research;

- general market conditions relating to the diagnostics, applied testing, pharmaceutical and biotechnology industries; and
- impact from foreign exchange rates.

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

Holders of our Common Shares should not expect to receive dividend income.

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

Holders of our Common Shares may not benefit from continued stock repurchase programs.

Between October 2012 and April 2013, we repurchased a total of 5.1 million of our Common Shares for an aggregate cost of $99.0 million, and between September 2013 and June 2014, we repurchased an additional 4.4 million of our Common Shares for $100.4 million (including performance fees). In 2014 and 2015, we repurchased a total of 2.9 million Common Shares for an aggregate cost of $69.9 million under our third share repurchase program. The purpose of these repurchases has been to hold the shares in treasury in order to satisfy obligations from exchangeable debt instruments and/or employee share-based remuneration plans and thus to reduce dilution to our existing Common Share holders. We may decide not to continue such programs in the future, the covenants we have with our lenders may limit our ability to use available cash to do so, and the market price of our Common Shares may make such repurchases less desirable. In any of these cases, our Common Share holders may suffer dilution from conversion of our indebtedness or issuance of shares pursuant to employee remuneration plans that would otherwise be at least partially offset by repurchased shares.

Future sales and issuances of our Common Shares could adversely affect our stock price.

Any future sale or issuance of a substantial number of our Common Shares in the public market, or any perception that a sale may occur, could adversely affect the market price of our Common Shares. Under Dutch law, a company can issue shares up to its authorized share capital provided for in its Articles of Association. Pursuant to our Articles of Association, our authorized share capital amounts to EUR 9.0 million, which is divided into 410.0 million common shares, 40.0 million financing preference shares and 450.0 million preference shares, with all shares having a EUR 0.01 par value. As of December 31, 2015, a total of approximately 233.0 million Common Shares were outstanding along with approximately 10.8 million additional shares reserved for issuance upon exercise or release of outstanding stock options and awards, of which 1.7 million were vested. A total of approximately 19.7 million Common Shares are reserved and available for issuances under our stock plans as of December 31, 2015, including the shares subject to outstanding stock options and awards. The majority of our outstanding Common Shares may be sold without restriction, except shares held by our affiliates, which are subject to certain limitations on resale. Additionally, the Warrants issued in connection with the Cash Convertible Notes Call Spread Overlay cover an aggregate of 25.8 million shares of our common stock (subject to anti-dilution adjustments under certain circumstances).

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

We may be classified as a “passive foreign investment company,” or a PFIC, for U.S. federal income tax purposes if certain tests are met. Our treatment as a PFIC could result in a reduction in the after-tax return to holders of Common Shares and would likely cause a reduction in the value of these shares. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to our U.S. shareholders. We would be considered a PFIC with respect to a U.S. shareholder if for any taxable year in which the U.S. shareholder held the Common Shares, either (i) 75% or more of our gross income for the taxable year is passive income; or (ii) the average value of our assets (during the taxable year) which produce or are held for the production of passive income is at least 50% of the average value of all assets for such year. Based on our income, assets and activities, we do not believe that we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2015, and do not expect to be a PFIC for the current taxable year or any future taxable year. No assurances can be made, however, that the Internal Revenue Service will not challenge this position or that we will not subsequently become a PFIC. In countries outside the U.S., other or similar tax regimes may apply and result in unfavorable tax treatment for any dividends received.

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

Our Articles of Association (Articles) provide that our shareholders may only suspend or dismiss our Managing Directors and Supervisory Directors against their wishes with a vote of two-thirds of the votes cast if such votes

represent more than 50% of our issued share capital. If the proposal was made by the joint meeting of the Supervisory Board and the Managing Board, a simple majority is sufficient. The Articles also provide that if the members of our Supervisory Board and our Managing Board have been nominated by the joint meeting of the Supervisory Board and Managing Board, shareholders may only overrule this nomination with a vote of two-thirds of the votes cast if such votes represent more than 50% of our issued share capital.

Certain other provisions of our Articles allow us, under certain circumstances, to prevent a third party from obtaining a majority of the voting control of our Common Shares through the issuance of Preference Shares. Pursuant to our Articles and the resolution adopted by our General Meeting of Shareholders, our Supervisory Board is entitled to issue Preference Shares in

case of an intended takeover of our company by (i) any person who alone or with one or more other persons, directly or indirectly, have acquired or given notice of an intent to acquire (beneficial) ownership of an equity stake which in aggregate equals 20% or more of our share capital then outstanding or (ii) an "adverse person" as determined by the Supervisory Board. If the Supervisory Board opposes an intended takeover and authorizes the issuance of Preference Shares, the bidder may withdraw its bid or enter into negotiations with the Managing Board and/or Supervisory Board and agree on a higher bid price for our Shares.

In 2004, we granted an option to the Stichting Preferente Aandelen QIAGEN, or the Foundation (Stichting), subject to the conditions described in the paragraph above, which allows the Foundation to acquire Preference Shares from us. The option enables the Foundation to acquire such number of Preference Shares as equals the number of our outstanding Common Shares at the time of the relevant exercise of the option, less one Preference Share. When exercising the option and exercising its voting rights on these Preference Shares, the Foundation must act in our interest and the interests of our stakeholders. The purpose of the Foundation option is to prevent or delay a change of control that would not be in the best interests of us and our stakeholders. An important restriction on the Foundation's ability to prevent or delay a change of control is that a public offer must be announced by a third party before it can issue (preference or other) protective shares that would enable the Foundation to exercise rights to 30% or more of the voting rights without an obligation to make a mandatory offer for all shares held by the remaining shareholders. In addition, the holding period for these shares by the Foundation is restricted to two years, and this protective stake must fall below the 30% voting rights threshold before the two-year period ends.

Note Regarding Forward-Looking Statements and Risk Factors

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

Item 4. Information on the Company

Description of our business

Company overview

QIAGEN is a global leader in Sample to Insight solutions that transform biological samples into valuable molecular insights. Our vision is to make improvements in life possible by enabling our customers in four broad classes - Molecular Diagnostics, Applied Testing, Pharma and Academia - to achieve outstanding success and breakthroughs using reliable and efficient Sample to Insight solutions.

Sample to Insight solutions are composed of sample and assay technologies, bioinformatics and automation systems. Our solutions support more than 500,000 customers worldwide in generating insights into the molecular building blocks of life. More than two billion biological samples have been prepared or analyzed using QIAGEN sample technologies. Our proven solutions are providing answers in hospitals and laboratories worldwide, integrated with bioinformatics to make sense of the increasing volumes and complexity of data.

Since the first sequencing of the human genome was completed in 2003, an explosion in genomic discoveries has launched what observers are calling "the Century of Biology." Dramatic acceleration in the speed of sequencing - and

reduction in cost - is generating vast quantities of genomic data and new discoveries in biology. This growing knowledge of the molecular basis of life, its mechanisms and diseases, is driving a revolution in research and influencing many areas of everyday life. QIAGEN's mission is to drive this era of discoveries and the wide-ranging practical applications they are spawning for the future.

QIAGEN began operations in 1986 as a pioneer in the emerging biotechnology sector, introducing a novel method that standardized and accelerated extraction and purification of nucleic acids from biological samples. As molecular biology has grown to influence many areas of life, QIAGEN has expanded to serve the full spectrum of market needs. Our sample

technologies are unmatched in quality for isolating and preparing DNA (deoxyribonucleic acid), RNA (ribonucleic acid) and proteins from blood or other liquids, tissue, plants or other materials. Our assay technologies amplify, enrich and make these biomolecules visible for analysis, such as identifying the DNA of a virus or a gene mutation in a tumor. QIAGEN's industry-leading bioinformatics solutions interpret data to provide relevant, actionable insights. Our automation platforms tie these together in seamless and cost-effective molecular testing workflows - from Sample to Insight.

Net sales of $1.28 billion in 2015 were comprised of consumable kits and other revenues (87% of sales) and automated systems and instruments (13% of sales). Approximately 50% of net sales in 2015 were in Molecular Diagnostics, and 50% went to Life Sciences customer classes in the Academia, Pharma and Applied Testing markets.

QIAGEN has grown by introducing innovative products and making strategic acquisitions that address the rapidly evolving needs of customers to transform biological samples into valuable molecular insights. We have funded our growth through internally generated funds, debt offerings and private and public sales of equity securities. QIAGEN has global shares that 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 Hulsterweg 82, 5912 PL Venlo, The Netherlands, and our telephone number is +31-77-355-6600.

As a holding company, QIAGEN conducts business through subsidiaries located throughout the world. Further information about QIAGEN can be found at 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.

Recent Developments

QIAGEN has achieved a number of recent strategic milestones in serving customers and growing our business.

Leadership in sample technologies continuing to drive growth:

- Building on our long-standing core strength in sample technologies, which labs around the world rely on to obtain highest-quality DNA and RNA for downstream analysis, we further expanded our offering in 2015 to maximize the value of our portfolio by addressing additional front-end issues for customers. QIAGEN is pioneering "liquid biopsies" to unlock valuable molecular insights from body fluids such as blood rather than surgical biopsies. We also continue to add cutting-edge technologies to address particularly difficult sample challenges in life science research.
- In 2015 we expanded our pipeline by acquiring the innovative AdnaGen technology, which enables enrichment and molecular analysis of circulating tumor cells (CTCs) from blood samples. CTCs are pivotal to understanding the biology of cancer, and they hold promise to help guide treatment decisions, evaluate disease burden and monitor tumor progression.
- We also partnered with Cell Microsystems for exclusive rights to commercialize the CellRaft Array technology, considered the most cost-efficient, viable technology for isolation and analysis of single cells, a rapidly emerging area of research. The addition complements QIAGEN's existing single-cell portfolio that includes the REPLI-g product line.
- In late 2015 we acquired MO BIO Laboratories, a leader in technologies to analyze the impact of microbial diversity. Studies of the microbiome and metagenomics, enabled by next-generating sequencing, are increasingly important because of the impact microorganisms exert on human health and the environment. MO BIO's proprietary technology for isolating nucleic acids from challenging samples such as soil, water, plants, skin and feces addresses a critical need for laboratories. QIAGEN has launched a range of new products for microbiome analysis, from sample technologies to bioinformatics.

QuantiFERON-TB Gold growing briskly as world focuses on tuberculosis control:

- The QuantiFERON-TB Gold (QFT) and QuantiFERON-TB Gold Plus (QFT-Plus) tests for latent tuberculosis infection again delivered rapid growth in 2015. Our novel QuantiFERON-TB technology has become the latent TB test of choice with high market shares around the world - and about 80% market share in Europe. Our modern QuantiFERON-TB technology is displacing the century-old tuberculin skin test (TST) in screening for TB infection.
- Active tuberculosis (TB), a severe infectious disease that can be fatal if untreated, often results from "reactivation" of latent TB, an asymptomatic phase of the infection that can lie dormant for years. TB control programs are increasingly

screening vulnerable subpopulations and treating those infected with latent TB to prevent the emergence of the active, contagious disease. Using a small blood sample, QFT or QFT-Plus are more reliable than skin tests in detecting latent TB.

- In February 2015, groundbreaking clinical data on QuantiFERON-TB Gold was published in The Lancet. Testing more than 21,000 people in China, the study demonstrated that QFT provided more accurate diagnosis than the tuberculin skin test. The authors recommended community-based screening of at-risk populations with a modern blood test such as QFT.
- QuantiFERON-TB Gold Plus, the fourth generation of our market-leading test, gained momentum in 2015 after receiving

CE-IVD clearance in late 2014 for sale in 30 European countries. U.S. development and regulatory efforts are ongoing.

- Adoption of the QuantiFERON technology continues to spread. The National Health System (NHS) in England selected QFT-Plus for use in laboratory testing tenders as part of its TB control initiatives. In Germany, authorities recommended modern blood tests such as QFT and QFT-Plus after a large influx of Middle Eastern refugees, one of the vulnerable subpopulations in need of TB screening, depleted supplies of the only approved source of tuberculin skin tests. The U.S. Occupational Safety and Health Administration cited QFT in a directive on TB testing of healthcare workers.
- QuantiFERON Monitor (QFM) was launched in Europe in 2015 for initial use in transplant patients as a standardized, cost-effective measurement of immune system response.

Next-generation sequencing solutions extending QIAGEN's reach:

- In late 2015 we introduced the GeneReader NGS System, the first complete Sample to Insight next-generation sequencing (NGS) solution designed for any laboratory to deliver actionable results. The platform is the world's first truly end-to-end NGS workflow from primary sample to a final report - providing a simpler, more cost-effective way for clinical testing to take advantage of NGS technology and improve outcomes.
- The GeneReader NGS System has gained positive customer feedback. At its rollout during the Association for Molecular Pathology (AMP) 2015 Annual Meeting, the Broad Institute of MIT and Harvard presented an analysis demonstrating the accuracy of the platform through a head-to-head comparison with other molecular testing systems.
- With the GeneReader NGS System we introduced our new Actionable Insights Tumor Panel, the first in a family of GeneRead QIAact Panels. The novel gene panel targets 12 clinically actionable genes that are often analyzed in prevalent types of cancer, including breast, ovarian, colorectal, lung and melanoma. The panel can detect up to 1,250 different genetic mutations in a sample. The panel is integrated with QIAGEN Clinical Insight software to access the latest data on relevant variants using the QIAGEN Knowledge Base, the industry's largest collection of human-curated genomic findings and literature.
- We integrated the Enzymatics technology and consumables portfolio, which we acquired in December 2014, into our offering of universal NGS products. Enzymatics products are used in an estimated 80% of all next-generation sequencing workflows.

Leadership in Personalized Healthcare gaining further momentum:

- QIAGEN continues to roll out novel companion diagnostics that deliver insights enabling personalized treatment decisions based on patients' individual genomic information. Our Personalized Healthcare pipeline is gaining momentum through new collaborations with Pharma companies, expanding platform options and the licensing of novel biomarkers.
- The therascreen® EGFR RGQ PCR Kit received U.S. regulatory approval in 2015 to guide the use of AstraZeneca's IRESSA® (gefitinib) in patients with advanced or metastatic non-small cell lung cancer (NSCLC). A U.S. regulatory submission also was completed for this kit, to guide the use of Clovis Oncology's proposed targeted therapy rociletinib, for the treatment of patients with NSCLC harboring a T790M mutation in the EGFR gene.
- In 2015 QIAGEN's therascreen EGFR RGQ Plasma PCR kit received CE-IVD marking as the first-ever liquid biopsy-based companion diagnostic to gain regulatory clearance for use in lung cancer patients. We have other co-development efforts underway to commercialize companion diagnostics based on non-invasive liquid biopsies.
- QIAGEN and Biotype Diagnostics GmbH entered into a partnership to develop and commercialize molecular diagnostic workflows, especially for companion diagnostics, based on QIAGEN's Modaplex platform. The system enables customers to detect, characterize and measure up to 100 parameters simultaneously.
- An agreement with Columbia University provided exclusive rights for diagnostics based on fusions of the fibroblast growth factor receptor (FGFR) and transforming acidic coiled-coil (TACC) genes in various cancers. The program is synergistic with our pipeline, including development of companion diagnostics based on the IDH1 and IDH2 biomarkers.

Collaborations with Pharma expanding to drive growth in Personalized Healthcare:

- As the world's leading independent developer of molecular technologies, QIAGEN is the preferred partner for pharmaceutical and biotech companies to develop and commercialize companion diagnostics paired with targeted

drugs. In 2015 we initiated a record number of co-development projects with existing and new partners and reached a milestone of 15 master collaboration agreements, each enabling multiple projects. These partnerships add to our pipeline of companion diagnostics to be commercialized in the future, following clinical trials and regulatory approvals along with the drugs.

- In 2015, we launched collaborations for co-development of tests based on several cancer-related biomarkers including IDH1/2, FGFR, BRCA, BRAF and PI3K, using a range of different detection technologies including PCR, Modaplex, QuantiFERON and next-generation sequencing (NGS).

- Most of these collaborations are undisclosed at the request of the Pharma partners. One recently announced program will commercialize a non-invasive companion diagnostic for a novel Tokai Pharmaceuticals drug compound that is in late-stage trials for treatment of castration-resistant prostate cancer, using our new AdnaGen circulating tumor cell technology. Another new partnership begins with development of a companion diagnostic paired with a targeted compound from Array BioPharma that is currently in Phase III clinical trials for use in patients with NRAS-mutant melanoma.

QIAsymphony delivering platform growth as content menu expands:

- QIAGEN achieved our 2015 goal of surpassing 1,500 cumulative placements of the flexible modular QIAsymphony platform, up from 1,250 at the end of 2014. The flexible QIAsymphony platform offers customers Sample to Insight automation for medium-throughput molecular testing workflows. The larger installed base and expanding content menus drove our 2015 growth in consumables.
- We continue to expand the QIAsymphony content menu to enhance the instruments' value to customers worldwide. In 2015, we launched seven new diagnostic tests with European approval to run on the Rotor-Gene Q (RGQ) real-time PCR platform, in the QIAsymphony family. The first multiplex assay for the platform, the RespiFast RG Panel, launched with CE-IVD marking for detection and differentiation of 18 viruses and four bacteria in acute upper respiratory tract infections.
- We are advancing a pipeline of more than 30 development projects for QIAsymphony, including the growing menu of infectious disease tests in the artus portfolio in Europe and the U.S. We are also expanding our Applied Testing content: investigator tests for human ID / forensics, cador for veterinary medicine and mericon for food safety. In veterinary labs, a mericon test was deployed to help combat the global spread of an H5N8 strain of avian influenza A among poultry.
- We entered a collaboration with Seegene Inc. to develop a menu of multiplex assay panels for the QIAsymphony platform, using Seegene technologies that enable real-time PCR analysis of up to 20 target genes per tube in a single reaction. The first project is to develop comprehensive panels to profile infectious diseases.
- The QIAsymphony platform serves all of our customer classes: Approximately 60% of current placements are in Molecular Diagnostics, and 40% are in the Life Sciences with Applied Testing, Pharma and Academia customers.

Industry-leading bioinformatics turning raw genomic data into valuable insights:

- QIAGEN's Bioinformatics portfolio delivered strong double-digit growth in 2015, enabling users to gain valuable insights from sequencing data with the industry-leading portfolio of information resources and software solutions. Our tools turn vast amounts of genomic data into actionable insights for customers, addressing a critical bottleneck in next-generation sequencing, especially for clinical research and diagnostics. We continue to roll out new solutions to meet specialized needs in research and healthcare and to integrate rich bioinformatics with QIAGEN's molecular testing workflows.
- The global introduction of QIAGEN Clinical Insight (QCI) in 2015 added momentum with a unique evidence-based clinical decision support solution that streamlines the annotation, interpretation and reporting of NGS results for clinical laboratories. QCI is a software and content platform that draws insights on complex genomic variants from the QIAGEN Knowledge Base. Applications of QCI expanded as 2015 progressed, from interpreting NGS data on somatic mutations in solid tumor cancers, to hereditary cancer indications, as well as leukemia and lymphoma testing.
- Our bioinformatics solutions gained broader commercial presence through reseller agreements with BGI, the world's largest genomics organization, and GATC Biotech, a leading provider of DNA and RNA sequencing services worldwide, by providing their clients access to our Ingenuity Variant Analysis solution. This powerful analysis and interpretation platform enables customers to efficiently evaluate complex genomic data in a secure, cloud-based environment.
- We co-founded a coalition of 13 leading life science and diagnostics organizations to create and launch the Allele Frequency Community, an extensive, high-quality collection of digitized human genomes. The data is stored on QIAGEN's secure IT infrastructure, and researchers can explore it using Ingenuity Variant Analysis.
- QIAGEN became the exclusive partner to commercialize a new database containing more than 7,000 highly annotated whole genomes from Inova Genomes. Providing researchers with a unique, diverse compendium of sequences, this database is available through Ingenuity Variant Analysis and the CLC Biomedical Genomics Workbench.

- The CLC Microbial Genomics Module was launched to enable academic and commercial researchers focused on food production, agricultural biology and infectious diseases to visually explore and analyze microbiomes.
- We introduced a new hereditary disease solution to accelerate solve rates in diagnostic odyssey cases by enabling researchers to focus on the right causal candidates. The offering includes QIAGEN's Biomedical Genomics Workbench, Biomedical Genomics Server Solution, Ingenuity Variant Analysis and HGMD Human Gene Mutation Database.

Our Products

QIAGEN leverages our leadership in Sample to Insight molecular technologies across a wide range of applications and

customer classes through more than 500 core consumable products (sample and assay “kits”), as well as instruments that automate the use of these products for sample preparation, analysis and interpretation. Our bioinformatics solutions connect laboratory workflows and process extensive amounts of genomic data, reporting relevant insights to enable scientists or clinicians to decide on further action.

QIAGEN’s diverse revenue streams can be seen in two main categories: consumables and related revenue, and automation platforms and instruments.

Consumables and related revenues

Consumable products, accounting for approximately 79%-83% of net sales, typically include sample technologies that contain tools and ingredients to extract and purify molecules of interest from biological samples and assay technologies that make the information in these genomic molecules available for analysis and interpretation. To maximize customer convenience and reduce user error, these kits contain all necessary reagents and buffers and a manual of protocols and background information.

Reliability, standardization, ease of use and cost-effectiveness are key to the success of commercial products in molecular testing laboratories. QIAGEN sample technologies ensure that a biological sample is processed in a highly reproducible, standardized method with the highest level of quality to allow accurate analysis. Our assay technologies are either generic or pre-designed, with each kit including reagents to enable customers to target molecules of interest for detection on platforms such as polymerase chain reaction (PCR) or next-generation sequencing (NGS). Each kit is sufficient to support a number of applications, varying from kits containing a single application to kits containing more than 1,000 applications per kit.

Our sample technologies are used to isolate, purify and stabilize nucleic acids and proteins. Applications include plasmid DNA purification, RNA purification and stabilization, genomic and viral nucleic acid purification, DNA cleanup after PCR and sequencing, and library preparation for sequencing. We are the leader in sample technology kits to enable minimally-invasive liquid biopsies based on blood or other body fluids. Our assay technologies enable detection of specific or open molecular targets. Applications include open, general purpose PCR reagents or kits for the specific detection of viral or bacterial pathogens and parasites in humans and animals, pharmacogenomic testing and genotyping, as well as a growing portfolio of gene panels enabling next-generation sequencing to identify genetic mutations relevant to clinical or research targets in diseases such as cancer.

Related revenues, accounting for approximately 4%-8% of our net sales, include bioinformatics solutions, including the Ingenuity, CLC bio and BIOBASE portfolios acquired in 2013 and 2014. QIAGEN bioinformatics are sold as freestanding solutions and also, increasingly, integrated with QIAGEN consumables and instruments for seamless Sample to Insight workflows. Examples of our bioinformatics solutions:

The QIAGEN Knowledge Base is a deep repository of expertly curated biological interactions and functional annotations covering millions of relationships between proteins, genes, complexes, cells, tissues, drugs and diseases. This resource, which is updated continually, provides powerful content and context for a number of our bioinformatics solutions.

Ingenuity Variant Analysis provides a powerful cloud-based platform to efficiently evaluate data generated by high-throughput NGS technologies. Tapping into the QIAGEN Knowledge Base, it quickly filters genetic variants from testing to identify those most likely to cause disease.

QIAGEN Clinical Insight is a unique evidence-based clinical decision support solution which was introduced in 2015. This software and content platform, drawing on the QIAGEN Knowledge Base, delivers clinically relevant insights from complex genomic variants identified in NGS. Applications involve tests for somatic and hereditary cancer, leukemia and lymphoma.

CLC Genomics Workbench is a comprehensive analysis package for the analysis and visualization of data from all major NGS platforms. The software incorporates cutting-edge technology and algorithms, supporting key NGS features within genomics, transcriptomics and epigenomics research fields.

GeneGlobe, our web-based portal that enables researchers to search and select from more than 31 million pre-designed and custom PCR assay kits and NGS assay panels, includes genome-wide solutions for 28 species with any gene or pathway of interest.

Related revenues also include royalties, milestone payments from co-development agreements with pharmaceutical companies, payments from technology licenses and patent sales, and 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, contributing approximately12%-13% of net sales together with related services and contracts, automate the use of consumables into efficient workflows for a broad range of laboratory needs.

QIAGEN platforms are designed to carry our customers from Sample to Insight - handling and preparation of biological samples, analysis using sequencing technologies, all the way to interpretation that delivers valuable insights. These instruments enable laboratories to perform reliable and reproducible processes, including nucleic acid sample preparation, assay setup, target detection, and interpretation of genomic information.

Among the automation platforms that contribute to QIAGEN's business:

QIAsymphony is an easy-to-use modular system that has launched a new era of integrated workflow and laboratory automation, making molecular testing more efficient and helping to disseminate standardized, clinically proven molecular diagnostics. Our fully integrated QIAsymphony RGQ, launched in 2010, includes three modules - QIAsymphony SP for sample preparation, QIAsymphony AS for assay setup, and our real-time PCR platform Rotor-Gene Q. In 2015, our installed base increased to more than 1,500 QIAsymphony systems worldwide, more than triple the number at the end of 2010. The platform offers many features to enhance workflows, such as continuous loading, random access and the ability to process an almost unlimited range of sample types. QIAsymphony has the broadest content menu in its category in Europe and other markets, and QIAGEN is developing more regulator-approved assays to add value for customers.

Rotor-Gene Q, the world's first rotary real-time PCR cycler system, uses real-time PCR reactions to make sequences of DNA and RNA visible through amplification and quantifiable. It is an integral component of QIAsymphony RGQ.

GeneReader NGS System, introduced in 2015, is the first complete Sample to Insight next-generation sequencing (NGS) solution designed for any laboratory to deliver actionable results. This innovative platform provides a simpler, more cost-effective way for clinical testing to take advantage of NGS technology and improve outcomes. The GeneReader NGS System offers the flexibility of scalable batch sizes and continuous loading of multiple flow cells, and customers can create relevant reports using QIAGEN's proven gene panels and bioinformatics solutions. All parts of the NGS workflow, from handling of primary samples through sequencing to final reports, are provided by QIAGEN's Sample to Insight system.

Modaplex is a multimodal automation system integrating amplification, capillary electrophoresis and real-time qPCR quantification of multiple targets in a single reaction. This innovative platform allows up to 48 samples, including multiple targets and different types of assays, to run simultaneously in a single well.

EZ1 Advanced XL performs automated nucleic acid purification for a wide range of sample types relevant for molecular diagnostics, human identity testing, forensics, biomedical research, and gene expression analysis.

QIAcube is an award-winning sample processing instrument that incorporates novel and proprietary technologies allowing users to fully automate the use of almost all QIAGEN technologies originally designed for manual processing of samples.

QIAcube HT enables automated mid- to high-throughput nucleic acid purification in 96-well format using silica membrane technology. Users can quickly and easily purify DNA, RNA, and miRNA from almost any type of sample — including cells, tissues, and food material, as well as from bacteria and viruses in animal samples.

PyroMark is a high-resolution detection platform with Pyrosequencing technology that enables real-time analysis and quantification of genetic mutations and DNA methylation patterns. This technology can be of great value, as it allows users to identify previously unknown mutations or variations, run multiplex analysis for genetic and pathogen detection, or conduct epigenetic research.

QIAgility is a compact benchtop instrument that enables rapid, high-precision PCR setup. The unmatched versatility of the QIAgility means that almost all tube and plate formats are supported, as well as Rotor-Discs for the Rotor-Gene Q.

QIAxcel replaces traditional slab-gel analysis, eliminating time-consuming nucleic acid separation methods in low- to high-throughput laboratories. QIAxcel offers unprecedented sensitivity and time-to-results for analysis of DNA fragments and RNA.

ESEQuant instruments enable Point of Need testing in healthcare and other applications. These portable, battery-operated optical measurement devices permit low-throughput molecular testing in physician practices, emergency rooms, remote areas, and other settings with limited or delayed access to laboratory infrastructure.

Customers

From the early days of the biotechnology revolution, QIAGEN believed that innovative technologies for the preparation of samples and the analysis of nucleic acids would play an increasingly important role in cutting-edge

biology - and that insights extracted from DNA and RNA would be increasingly valuable in research, industry and healthcare.

With a growing portfolio of innovative products for molecular testing, we have built deep customer relationships across the life science value chain. Discoveries often surface in universities and research institutes and are published, then find resources for development by pharmaceutical and biotech companies, and finally move into widespread commercial use in healthcare and other areas of life. We serve the needs of four major customer classes:

- Molecular Diagnostics - healthcare providers engaged in 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 - pharmaceutical and biotechnology companies using molecular testing to support drug discovery, translational medicine and clinical development efforts
- Academia - researchers exploring the secrets of life such as disease mechanisms and pathways, in some cases translating findings into drug targets or other products

Molecular Diagnostics

The ability of advanced diagnostic technologies to unlock molecular information for patients is changing the practice of medicine, creating a large and growing market for nucleic acid sample preparation, assay technologies and bioinformatics in clinical care. Dissemination of PCR and other amplification technologies has brought molecular diagnostics into routine use in healthcare around the world, and next-generation sequencing (NGS) is in the early days of further transforming healthcare.

Technologies for molecular diagnostics enable clinicians and labs to identify and profile microorganisms, cancer cells, bacteria and viruses by searching for their specific nucleic acid sequences or to characterize newly discovered genomic sequences related to diseases. Commercial applications are multiplying as researchers identify new biological markers for disease and develop novel technologies to decipher these diagnostic clues.

The molecular diagnostics market generates total sales estimated by industry experts at $5-6 billion in 2015, of which approximately $4 billion is potentially accessible to QIAGEN's current product portfolio. Molecular diagnostics is the most dynamic segment of the global in vitro diagnostics market and is expanding at a compound annual growth rate estimated in the high single-digits or low double-digits. Given the advantages of precise genetic information over traditional tests, QIAGEN expects the healthcare market to continue to provide significant growth opportunities.

QIAGEN’s growth among Molecular Diagnostics customers results from targeting four strategies for fighting disease:

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 - testing symptomatic patients to profile the precise type of disease, for example screening to differentiate viral or bacterial infections involved in blood-borne diseases and healthcare-associated infections. Profiling tests are particularly useful in at-risk patient groups, such as organ transplant patients.

Personalized Healthcare - using molecular tests to guide the selection of therapies, including landmark QIAGEN companion diagnostics 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 cancers and other diseases.

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.

QIAGEN offers one of the broadest portfolios of molecular technologies for healthcare. Success in Molecular Diagnostics depends on the ability to accurately analyze purified nucleic acid samples from sources such as blood, tissue, body fluids and stool, on automated systems that can process these samples very reliably and efficiently, often handling hundreds of samples concurrently. Other key factors are the range of assays for various diseases and biomarkers, convenience and ease of laboratory workflow, and reliability and standardization of lab procedures.

Our early-warning QuantiFERON®-TB Gold and QuantiFERON®-TB Gold Plus tests are leading the industry in screening to support tuberculosis control. Tuberculosis (TB) remains the largest killer of any infectious disease that sickens approximately 9 million people a year, causing 1.5 million deaths. The World Health Organization (WHO) estimates one-third of the global population is infected with tuberculosis but with no symptoms of active disease, a condition known as latent TB infection (LTBI). About 5-10% of patients with LTBI are at risk of eventually developing active, contagious TB disease and this risk is significantly higher in certain groups such as immunocompromised or those receiving immunosuppressive medications. QuantiFERON-TB Gold more accurately detects latent TB infection, helping inform clinicians in decisions to initiate preventative therapy, thereby in order to avoid progression to active TB. The potential global market for latent TB infection testing is estimated at up to $1 billion.

QIAGEN also is the global leader in screening technologies for HPV, a viral infection that is the primary cause of cervical cancer, which kills about 270,000 women a year. Our “gold standard” digene HC2 HPV Test and our emerging careHPV Test for use in low-resource regions of the world are important Prevention tests. The U.S. HPV business has declined to about 3% of

our total sales amid vigorous price competition, even as digene HC2 remains the market-leading test. In Europe and other regions, we are a leader in a growing HPV market based on clinical evidence and policy initiatives for fighting cervical cancer.

In Profiling, we offer an extensive range of kits for diagnosing infectious diseases, and we are expanding this portfolio by seeking regulatory approvals of new tests in additional markets. In 2015 we introduced new test kits for bacterial and viral infections with approvals in the United States, Europe or Canada, adding to the diagnostic toolkit of physicians and the content menu of assay technologies that will efficiently run on the QIAsymphony automation platform. Among the 2015 launches were artus® HSV1/2 kits for herpes simplex virus type 1 and type 2; the RespiFast RG Panel, a multiplex test for detection and differentiation of 18 viruses and four bacteria in acute upper respiratory tract infections; the RealStar® Filovirus Screen RT-PCR kit for Ebola, Marburg and related viruses; and several other tests for detection of blood-borne or respiratory viruses.

QIAGEN's test portfolio for Personalized Healthcare covers a broad range of technologies and biomarkers, including regulator-approved companion diagnostics for oncogenes such as KRAS and EGFR, as well as comprehensive gene panels for research applications in next-generation sequencing. In 2015 we launched the therascreen® EGFR RGQ Plasma PCR kit as the first CE-IVD liquid biopsy-based companion diagnostic test for EGFR mutation detection in lung cancer patients; the ipsogen® BCR-ABL1 Mbcr RGQ RT-PCR kit as the first commercial CE-IVD test to provide deep molecular response status for monitoring the BCR-ABL1 biomarker in chronic myelogenous leukemia; and the second FDA approval for the therascreen® EGFR RGQ PCR kit, to guide the use of AstraZeneca’s IRESSA® (gefitinib) in advanced or metastatic non-small cell lung cancer patients. A key element of our expansion in Personalized Healthcare is enabling laboratories to efficiently use these assay technologies on our QIAsymphony platform. We also are developing companion diagnostics for our GeneReader NGS System and Modaplex platform.

As the world’s leading independent developer of molecular technologies, QIAGEN is the preferred partner for pharmaceutical and biotech companies to develop and commercialize companion diagnostics paired with targeted drugs. In 2015, we initiated a record number of co-development projects with existing and new partners and reached a milestone of 15 master collaboration agreements, each enabling multiple projects. These partnerships add to our pipeline of companion diagnostics to be commercialized in the future, following clinical trials and regulatory approvals along with the drugs.

We market a range of automation systems for low-, medium-, and high-throughput nucleic acid sample processing, assay setup and analysis 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 market assays directly via QIAGEN's sales channels, and selected assays through major diagnostic partners or other 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. In 2015, QIAGEN launched our new investigator® STR assay kits for forensic laboratories in the United States as the first new entrant in 20 years in the U.S. market for STR kits, meeting an important need as the U.S. forensics community upgrades its standards.

Pharma

QIAGEN has deep relationships with pharmaceutical and biotechnology companies. Drug discovery and translational research efforts increasingly employ genomic information, both to guide research in diseases and to differentiate patient populations most likely to respond to particular therapies. We estimate that about half of QIAGEN sales in this customer class support research, while the other half supports clinical development, including stratification of patient

populations based on genetic information. QIAGEN's bioinformatics solutions, including the GeneGlobe portal, Ingenuity Variant Analysis and CLC Cancer Research Workbench informatics products, also are widely used by scientists to guide their pharmaceutical research.

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 QIAGEN markets in our Molecular Diagnostics customer class. Healthcare professionals use companion diagnostics to test 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. A wave of newly discovered biomarkers and companion diagnostics has begun 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 marketing reach, and independence as a company focusing exclusively on these types of technologies.

Academia

QIAGEN provides Sample to Insight solutions to leading research institutions around the world. While many academic laboratories continue to use manual, labor-intensive methods for nucleic acid separation and purification, QIAGEN has focused on enabling labs to replace time-consuming traditional methods with reliable, fast, highly reproducible, and high-quality nucleic acid extraction and purification technologies. QIAGEN often partners with leading institutions in research projects.

As academic institutions increasingly embrace translational research, bridging from discoveries to practical applications in medicine, our relationships in Academia also support 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.

Global Presence by Category of Activity and Geographic Market

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 including bioinformatics solutions, and revenues derived from instrumentation sales.

(in thousands)	2015	2014	2013
Net Sales			
Consumables and related revenues	$1,114,580	$1,172,728	$1,140,203
Instrumentation	166,406	172,049	161,781
Total	$1,280,986	$1,344,777	$1,301,984

Geographical Information

QIAGEN currently markets products in more than 130 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 customer, as certain subsidiaries have international distribution):

(in thousands)	2015	2014	2013
Net Sales			
Americas:			
United States	$525,532	$543,877	$545,600
Other Americas	79,578	75,974	80,299
Total Americas	605,110	619,851	625,899
Europe, Middle East and Africa	409,955	451,092	416,334
Asia Pacific and Rest of World	265,921	273,834	259,751
Total	$1,280,986	$1,344,777	$1,301,984

QIAGEN has built an increasing presence in key emerging markets as a growth strategy. In 2015, the top seven emerging markets contributed approximately 15% net sales, advancing over weaker years in 2013 and 2014. Strong 2015 sales in Turkey, China, South Korea and India more than offset slowdowns in Mexico and Russia. China is our third-largest country by sales.

Growth Drivers and Key Catalysts

We believe the combined global market for molecular diagnostics and molecular life science research products totals approximately $15 billion. Driving the industry's long-term growth are ongoing breakthroughs and insights into molecular biology, the emergence of next-generation sequencing, bioinformatics to analyze and interpret molecular information, use of diagnostics to improve healthcare quality and reduce costs, and revenue streams made possible through consumable products.

We have grown substantially with a flexible strategy to accelerate innovation and growth by developing innovative new platforms, consumables and bioinformatics products, partnering with researchers and Pharma companies, and acquiring companies or technologies to complement our portfolio.

We are building momentum by continuing to focus on strategic growth drivers and key catalysts:

1. Sample Technologies: Our growing portfolio of Sample to Insight solutions leverages QIAGEN's recognized global

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leadership in technologies to extract and isolate DNA and RNA from biological samples. In 2015 we further expanded our sample technologies by adding innovative technologies to enable “liquid biopsies” and cutting-edge research.

2. QuantiFERON-TB: The modern standard for detecting latent tuberculosis infection, our QuantiFERON-TB Gold aids tuberculosis control by targeting subpopulations of at-risk patients in the United States, Europe and Asia. In 2015 we introduced QuantiFERON-TB Gold Plus, adding new technology to deliver even higher sensitivity and specificity in patients at greatest risk for TB infection, such as HIV-infected and other immunocompromised individuals.

3. Next-generation sequencing: Our strategic initiative to drive NGS adoption in clinical research and diagnostics gained further momentum in 2015 with the introduction of our innovative GeneReader NGS System, providing a simpler, more cost-effective way for any laboratory to take advantage of NGS technology and improve outcomes. We also offer a broad portfolio of “universal” solutions for NGS users.

4. Personalized Healthcare: We continue to develop and introduce companion diagnostics to guide the treatment of cancer and other diseases, as well as innovative sample technologies to support the care of patients. We also are a leading partner for pharmaceutical companies in co-developing products for personalized medicine.

5. QIAsymphony: We are driving global adoption of the QIAsymphony automation platform, surpassing our target of 1,500 cumulative placements in 2015, and expanding the content menu of test kits for the platform. Growing QIAsymphony placements and offering a broad menu of innovative consumables together drive sales growth.

6. Bioinformatics: Our industry-leading bioinformatics portfolio is growing rapidly as users of next-generation sequencing seek solutions for handling huge amounts of genomic data. Following the acquisitions of Ingenuity and CLC bio in 2013 and BIOBASE in 2014, we are expanding their software solutions, adding new applications and content for knowledge bases, and integrating them with QIAGEN products to create Sample to Insight workflows.

Research and Development

We are committed to expanding our global leadership in Sample to Insight solutions for molecular testing in healthcare and the life sciences. 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 clinicians 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 novel “content” - including assays to detect and measure biomarkers for disease or genetic identification.
- Integrating bioinformatics with the testing process - software and cloud-based resources to interpret and transform raw molecular data into useful insights.

Our research and development investments are among the highest in our industry. More than 1,000 employees in research and development work in nine QIAGEN centers of excellence on three continents. Our comprehensive intellectual property portfolio spans more than 1,700 granted patents and more than 800 pending applications.

Innovations in instrumentation are strengthening our leadership in the automation of laboratories, driving dissemination of molecular testing in healthcare and other fields, and generating increased demand for our consumable products. We continue to extend our modular QIAsymphony platform, enabling hospitals and other customers to adopt or greatly expand their use of molecular diagnostics. Building on the QIAsymphony platform, we plan to integrate additional modules for needs such as next-generation sequencing. QIAGEN also is developing a range of upgrades and enhancements for our GeneReader NGS System, which was introduced in 2015, to add further value for labs by addressing new applications and market segments. We also plan to introduce additional cancer-related gene panels, with longer-term expansion of the NGS content menu beyond oncology.

We are commercializing a deep pipeline of molecular assays for preventive screening and diagnostic profiling of diseases, assays for biomarkers to guide personalized medicine in cancer and other diseases, and tests for a broad range of other targets. An extensive development program has begun generating commercial launches of assays that add value to our QIAsymphony RGQ platform for Molecular Diagnostics and other uses. In addition, we are investing in co-development of companion diagnostics for Personalized Healthcare through projects with pharmaceutical and

biotech companies. In next-generation sequencing, we launched 14 new GeneRead™ DNAseq V2 gene panels in 2014, compatible with any NGS sequencer, as assays for an extensive range of cancer-related genes or gene regions. In Applied Testing, we continue 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.

Our bioinformatics teams are developing new software solutions and adding proprietary cloud-based resources to support the latest research and clinical trends in molecular testing, especially the interpretation of large volumes of data from next-generation sequencing. In addition, we are integrating these digital technologies with instruments and molecular content to provide our customers seamless Sample to Insight workflows.

Sales and Marketing

We market our products in more than 130 countries, mainly through subsidiaries in markets that we believe have the greatest sales potential in the Americas, Europe, Australia and Asia. Experienced marketing and sales staff, many of them scientists with academic degrees in molecular biology or related areas, sell our products and provide direct support to customers. Key accounts are overseen by business managers to ensure that we serve customers' commercial needs, such as procurement processes, financing, data on costs and value of our systems, and collaborative relationships. In many markets we have specialized independent distributors and importers.

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 service. One such tool is our technical service hotline, which allows existing or potential customers to discuss a wide range of questions about our products and related molecular biology procedures, via phone or email, with Ph.D. and M.Sc. scientists at QIAGEN. Frequent communication with customers enables us to identify market needs, learn about new developments and business opportunities, and respond with new products.

Our website (www.qiagen.com) and other digital channels make ordering easy with a full online product catalog and ordering. Our eCommerce team works with clients to provide automated processes supporting a wide variety of electronic transactions and all major eProcurement systems. Our website has full Japanese and Chinese language versions, plus some information in French, German and Korean. Information contained on our website, or accessed through it, is not part of this Annual Report.

Our GeneGlobe Genes & Pathways web portal (www.geneglobe.com) is a valuable outreach to scientists in Pharma and Academia, enabling researchers to search and order from more than 31 million PCR pre-designed assay kits and NGS assay panels. We have integrated GeneGlobe with our bioinformatics solutions, linking biological interpretation with ordering of the relevant laboratory assays to accelerate research.

We also distribute publications, including our catalog, to existing and potential customers worldwide, providing new product information, updates, and articles about existing and new applications. In addition, we hold numerous scientific seminars at clinical, academic and industrial research institutes worldwide. We conduct direct marketing campaigns to announce new products and special promotions, and we offer personalized electronic newsletters highlighting molecular biology applications.

For laboratories that frequently rely on our consumables, the QIAstock program maintains inventory onsite to keep up with their requirements. QIAGEN representatives make regular visits to replenish the stock and help with other needs. Easy-to-use online ordering, inventory monitoring and customer-driven changes make QIAstock an efficient system for providing ready access to our products for the hundreds of customers worldwide who use this program.

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, 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 2015, our purchases of intangible assets totaled $19.7 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, 2015, we owned 298 issued patents in the United States, 199 issued patents in Germany and 1,234 issued patents in other major industrialized countries. We had 859 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.

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

Competition

In the Academic and Pharma 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 innovative technologies and products, offering a comprehensive solution for nucleic acid collection, pre-treatment, separation and purification needs and providing 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; Thermo Fisher and Promega Corp. for assay solutions and for transfection reagents; and Sigma-Aldrich Corp. and Thermo Fisher 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 in the United States 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. 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, Cepheid 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 reimbursement.

We do not believe our competitors typically have the same comprehensive approach to sample to insight solutions 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 technologies-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 subject to a variety of laws and regulations in the European Union, the United States and other countries. The level and scope of the regulation varies depending on the country or defined economic region, but may include, among other things, the research, development, testing, clinical trials, manufacture, storage, recordkeeping, approval, labeling, promotion and commercial sales and distribution, of many of our products.

European Union Regulations

In the European Union, in vitro diagnostic medical devices (IVDs) are regulated under EU-Directive 98/79/EC (IVD Directive) and corresponding national provisions. The IVD Directive requires that medical devices meet the essential requirements set out in an annex of the directive. These requirements include the safety and efficacy of the devices. According to the IVD Directive, the Member States presume compliance with these essential requirements in respect of devices which are in conformity with the relevant national standards transposing the harmonized standards of which the reference numbers have been published in the Official Journal of the European Communities. These harmonized standards include ISO 13485:2003, the quality standard for medical device manufacturers.

IVD medical devices, other than devices for performance evaluation, must bear the CE marking of conformity when they are placed on the market. The CE mark is a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation implementing the relevant European Directive. As a general rule, the manufacturer must follow the procedure of the EC Declaration of conformity to obtain this CE marking.

Each European country must adopt its own laws, regulations and administrative provisions necessary to comply with the IVD Directive. Member States may not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking according to the conformity assessment procedures. On September 26, 2012, the European Commission (EC) adopted a proposal for new EU regulations for medical devices and IVDs that if finalized will impose additional regulatory requirements on IVDs used in the EU. These new regulations are targeted to be approved in early 2016 with a 5 year implementation requirement. Once approved the entire EU IVD industry will have to undergo the transformation.

Other Country Specific Requirements

In many countries outside of the United States and the EU, coverage, pricing and reimbursement approvals are also required. Additionally many of the major markets are adopting regulations and requirements similar to U.S. Food and Drug Administration (FDA) which require additional submission activities and management of country specific regulatory requirements.

We are also required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act, its books and records provisions and its anti-bribery provisions.

U.S. Regulations

In the United States, in vitro diagnostic kits are subject to regulation by the FDA as medical devices and must be cleared or approved before they can be marketed. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. In addition, 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 required by the FDA.

In Vitro Diagnostics

The FDA regulates the sale or distribution of medical devices, including in vitro diagnostic test kits. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. 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, pre-market notification and adherence to the 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 post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to pre-market approval. All Class I devices are exempt from premarket review; most Class II devices require 510(k) clearance, and all Class III devices must receive premarket approval before they can be sold in the United States.

The payment of a fee to the FDA is usually required when a 510(k) notice or premarket approval application is submitted.

510(k) Premarket Notification. A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device", that is legally marketed in the United States and for which a premarket approval application (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.

The FDA generally issues a decision letter within 90 days of receipt of the 510(k) if it has no additional questions or sends a first action letter requesting additional information within 75 days. Most 510(k)s do not require clinical data for clearance, but a minority will. Requests for additional data, including clinical data, will increase the time necessary to review the notice. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may petition the FDA to make a risk-based determination of the new device and reclassify the new device as a Class I or Class II device. The FDA is currently reevaluating the 510(k) review process, and we cannot predict what if any changes will occur.

Premarket Approval. 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 (IDE) to the FDA and obtains approval 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 that is 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 there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved before changed medical device may be marketed.

Any products sold by us pursuant to FDA clearances or approvals will be subject to pervasive and continuing regulation by the FDA, including record keeping requirements, reporting of adverse experiences with the use of the device and restrictions on the advertising and promotion of our products. 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) clearance or PMA approval for new devices, withdrawal of 510(k) clearances and/or PMA approvals and criminal prosecution.

Regulation of Companion Diagnostic Devices

Diagnostic tests may be used in the determination of whether a drug should be prescribed for a patient, and are often referred to as in vitro companion diagnostic devices. On August 6, 2014, the FDA issued Guidance for Industry and Food and Drug Administrative Staff on In Vitro Companion Diagnostic Devices. The Guidance applies to in vitro diagnostic companion diagnostic devices that provide information that is essential for the safe and effective use of a corresponding therapeutic drug. However, a novel in vitro diagnostic test that provides information that is useful in, but not a determining factor for the safe and effective use of a therapeutic product, would not be considered an IVD companion diagnostic. The FDA expects that the therapeutic sponsor will address the need for an approved or cleared IVD Companion Diagnostic Device in its therapeutic product development plan. The sponsor of the therapeutic product can decide to develop its own IVD Companion Diagnostic Device, partner with a diagnostic device sponsor to

develop the appropriate IVD Companion Diagnostic Device, or explore modification of an existing IVD diagnostic device (its own or another sponsor's) to accommodate the appropriate intended use. The FDA has approved a number of drug/diagnostic device companions in accordance with the Guidance.

In September 2013, the FDA issued its final rule on the Unique Device Identifier. This rule now requires an additional registered identifier, including a special barcode, on all FDA regulated medical devices. The rule is implemented in phases with the first deadline of September 24, 2014 being established for all Class III medical devices. For QIAGEN, this impacted the hc2, QuantiFERON, and therascreen products. We established a task force to ensure that the deadline was met but this will place additional administrative and regulatory burden on us related to the annual reporting of compliance of these products to the new regulation. Class II and Class I products are required to have this same labeling by September 24, 2016 and 2018, respectively. QIAGEN was fully compliant with the initial phase of the new rule by the September 2014 deadline and we continue to work to ensure that we will be able to meet the remaining deadlines. The new rule will also require additional

compliance oversight now that it has been implemented. The requirements are now required to be confirmed as part of our annual reporting and PMA submissions. They are also assessed during site inspections by the U.S. FDA.

Some of our products are sold for research purposes in the U.S., and labeled "For Research Use Only" (RUO) or "for molecular biology applications." In November 2013, the FDA issued a final Guidance for Industry and Food and Drug Administration Staff entitled, "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only." In the Guidance, RUO refers to devices that are in the laboratory phase of development, and investigational use only, or IUO, refers to devices that are in the product testing phase of development. These types of devices are exempt from most regulatory controls. Because we do not promote our RUOs for clinical diagnostic use or provide technical assistance to clinical laboratories with respect to these tests, we believe that these tests are exempt from FDA's premarket review and other requirements. If the FDA were to disagree with our designation of any of these products, we could be forced to stop selling the product until we obtain appropriate regulatory clearance or approval. Further, we believe that some of our RUOs may be used by some customers in their laboratory-developed tests (LDTs), which they develop, validate and promote for clinical use. However, as previously noted, we do not promote these products for use in LDTs or assist in the development of the LDTs for clinical diagnostic use.

On October 3, 2014, the FDA published notices in the Federal Register formally announcing their release and the beginning of a 120-day public comment period, which ended on February 2, 2015, for the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), and Docket No. FDA-2011-D-0357 for Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs). In essence, the FDA is proposing to regulate Clinical Laboratory Improvement Act (CLIA) laboratories that provide LDT's that meet the definition of a Medical Device as stated in the Food, Drug, and Cosmetic Act. While the guidance is directed at CLIA laboratories it also has the potential to change the relationship between laboratories and manufacturers. It also proposes to impose quality systems controls and mechanisms, including submissions, on the laboratories. These are the identical requirements that are currently imposed on manufacturers as described in the prior paragraphs of this section. In January 2015, QIAGEN, along with many other companies and industry groups submitted comments and suggestions to the FDA regarding the Draft LDT Guidance. To date FDA has not finalized the Guidance. It is therefore, not possible to precisely assess potential impact until the Guidance is finalized. QIAGEN has an executive task force that is monitoring and participating in the draft process to insure the earliest possible awareness of developments related to the Draft Guidance.

HIPAA and Other Privacy and Security Laws

Numerous privacy and data security laws apply to personal information, including health information. These laws vary in their application. For example, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations (HIPAA), regulate the uses, disclosures and security of identifiable health information (protected health information or PHI) in the hands of certain health care providers, health plans or health care clearing houses (covered entities). HIPAA regulates and limits covered entities' uses and disclosures of PHI and requires the implementation of administrative, physical and technical safeguards to keep PHI secure. HIPAA also applies to organizations that create, receive, maintain or transmit PHI to provide services to or for or on behalf of covered entities (business associates). Business associates and certain of their subcontractors are required to comply with certain privacy and all of the security standards of HIPAA. Business associates and covered entities must also comply with breach notification standards established by HIPAA. The HIPAA breach notification standards require covered entities to notify affected individuals, the government, and in some cases, local and national media in the event of a breach of PHI that has not been secured by encryption. The breach notification standards require business associates to notify covered entity customers of their own breaches of unsecured PHI so that the relevant covered entity may make required notifications. If we were to act as a HIPAA covered entity or business associate, we would be subject to these obligations.

Almost all states have adopted data breach notification laws relating to the "personal information" of its residents. Personal information typically includes an individual's name or initials coupled with social security, financial account, debit, credit or state-issued identification number or other information that could lead to identity theft. There is significant variability under these laws, but most require notification to affected individuals (and some

require notification to the government) in the event of breach. Other laws of some states require that that we comply with data security obligations. These laws may apply to us when we receive or maintain personal information regarding individuals, including our employees.

Many states have also adopted genetic testing and privacy laws. These laws typically require a specific, written consent for genetic testing as well as consent for the disclosure of genetic test results and otherwise limit uses and disclosures of genetic testing results. A few states have adopted laws that give their residents property rights in their genetic information. We require the disclosure of whole genome sequences in order to analyze and interpret genomic data for research use by our customers. Most of our institutional and physician customers are covered entities under HIPAA and must obtain proper authorization or de-identify information so that we may provide services. When PHI is de-identified in accordance with HIPAA or when the disclosure of PHI is authorized by a patient, HIPAA does not impose any compliance obligations on the recipient, but our use and disclosure of the information may be limited by contract or the terms of the authorization.

We are subject to enforcement by state attorneys general who have authority to enforce state data privacy or security laws. Accordingly, we maintain an active privacy and data security program designed to address applicable regulatory compliance requirements.

Privacy and data security laws, including those relating to health information, are complex, overlapping and rapidly evolving. As our activities evolve and expand, additional laws may be implicated, for example, there are non-U.S. privacy laws that impose restrictions on the transfer, access, use, and disclosure of health and other personal information. All of these laws impact our business either directly or indirectly. Our failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact our business and future business plans. For example, we may be subject to regulatory action or lawsuits in the event we fail to comply with applicable privacy laws. We may face significant liability in the event any of the personal information we maintain is lost or otherwise subject to misuse or other wrongful use, access or disclosure.

Compliance with Fraud and Abuse Laws

We have to comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid.

Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits persons from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce:

- The referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or
- Purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by a government-sponsored healthcare program.

The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as gifts, certain discounts, waiver of payments, and providing anything at less than its fair market value. In addition, several courts have interpreted the law to mean that if “one purpose” of an arrangement is intended to induce referrals, the statute is violated.

The Anti-Kickback Statue is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services (OIG) has issued regulations, commonly known as "safe harbors." These safe harbors set forth certain requirements that, if fully met, will assure healthcare providers, including medical device manufacturers, that they will not be prosecuted under the Anti-Kickback Statute. Although full compliance with these safe harbor provisions ensures against prosecution under the Anti-Kickback Statute, full compliance is often difficult and the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. The statutory penalties for violating the Anti-Kickback Statute include imprisonment for up to five years and criminal fines of up to $25,000 per violation. In addition, through application of other laws, conduct that violates the Anti-Kickback Statute can also give rise to False Claims Act lawsuits, civil monetary penalties and possible exclusion from Medicare and Medicaid and other federal healthcare programs. In addition to the Federal Anti-Kickback Statute, many states have their own kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payment made by a government health care program but also with respect to other payors, including commercial insurance companies.

Other Fraud and Abuse Laws

The federal False Claims Act (FCA) prohibits any person from knowingly presenting, or causing to be presented, a false claim or knowingly making, or causing to made, a false statement to obtain payment from the federal government. Those found in violation of the FCA can be subject to fines and penalties of three times the damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false

claim. Actions filed under the FCA can be brought by any individual on behalf of the government, a "qui tam" action, and such individual, known as a "relator" or, more commonly, as a "whistleblower," who may share in any amounts paid by the entity to the government in damages and penalties or by way of settlement. In addition, certain states have enacted laws modeled after the FCA, and this legislative activity is expected to increase. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies, including medical device manufacturers, to defend false claim actions, pay damages and penalties or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of investigations arising out of such actions.

The OIG also has authority to bring administrative actions against entities for alleged violations of a number of prohibitions, including the Anti-Kickback Statute and the Stark Law. The OIG may seek to impose civil monetary penalties or exclusion from the Medicare, Medicaid and other federal healthcare programs. Civil monetary penalties can range from $2,000 to $50,000 for each violation or failure plus, in certain circumstances, three times the amounts claimed in reimbursement or illegal remuneration. Typically, exclusions last for five years.

In addition, we must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, all of which can also be triggered by violations of federal anti-kickback laws; the Health Insurance Portability and Accounting Act of 1996, which makes it a federal crime to commit healthcare fraud and make false statements; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

There are also an increasing number of state “sunshine” laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices. In addition, a federal law known as the Physician Payments Sunshine Act, now requires medical device manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The federal government discloses the reported information on a publicly available website. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Environment, Health and Safety

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials. For example, the U.S. Occupational Safety and Health Administration (OSHA) has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through needle stick injuries. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association.

Reimbursement

United States

In the United States, payments for diagnostic tests come from several sources, including third party payors such as health maintenance organizations and preferred provider organizations; government health programs such as Medicare and Medicaid; and, in certain circumstances, hospitals, referring laboratories or the patients themselves. For many years, federal and state governments in the United States have pursued methods to reduce the cost of these programs. For example, in 2010 the United States enacted major healthcare reform legislation known as the Patient Protection and Affordable Care Act (ACA). Such changes have had, and are expected to continue to have, an impact on our business. At present, Medicare payment rates are affected by across-the-board federal budget cuts commonly referred to as “sequestration”. Under sequestration, the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare and Medicaid, reduced Medicare payments to providers by 2% annually beginning in 2013 and through 2023.

Code Assignment. In the United States, a third-party payor's decisions regarding coverage and payment are impacted, in large part, by the specific Current Procedural Terminology, or CPT, code used to identify a test. The American Medical Association, or AMA, publishes the CPT, which is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of the CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services and therefore to ensure reliable nationwide communication among healthcare providers, patients, and third-party payors.

A manufacturer of in vitro diagnostic kits or a provider of laboratory services may request establishment of a Category I CPT code for a new product. Assignment of a specific CPT code ensures routine processing and payment for a

diagnostic test by both private and government third-party payors.

The AMA has specific procedures for establishing a new CPT code and, if appropriate, for modifying existing nomenclature to incorporate a new test into an existing code. If the AMA concludes that a new code or modification of nomenclature is unnecessary, the AMA will inform the requestor how to use one or more existing codes to report the test.

While the AMA's decision is pending, billing and collection may be sought under an existing, non-specific CPT code. A manufacturer or provider may decide not to request assignment of a CPT code and instead use an existing, non-specific code

for reimbursement purposes. However, use of such codes may result in more frequent denials and/or requests for supporting clinical documentation from the third-party payor and in lower reimbursement rates, which may vary based on geographical location.

In 2012, the AMA added 127 new CPT codes for molecular pathology services that became effective on January 1, 2013. These new CPT codes are biomarker specific and were designed to replace the previous methodology of billing for molecular pathology testing, which involved “stacking” a series of non-biomarker specific CPT codes together to describe the testing performed. The new CPT codes were issued final national reimbursement prices by CMS in November of 2013. These federal reimbursement amounts are widely acknowledged to be lower than the reimbursement obtained by the now outdated “stacking” method, but commercial payors and Medicare contractors are still in the process of solidifying their coverage and reimbursement policies for the testing described by these new CPT codes. The lower reimbursement amounts experienced in the field of molecular pathology testing may soon be extending to other codes on the Clinical Laboratory Fee Schedule as CMS begins to base CPT laboratory code payment on third party payer rates in 2017, per the Protecting Access to Medicare Act (PAMA) passed in April 2014.

Coverage Decisions. When deciding whether to cover a particular diagnostic test, private and government third-party payors generally consider whether the test is a contractual benefit and, if so, whether it is reasonable and necessary for the diagnosis or treatment of illness and injury. Most third-party payors do not cover experimental services. Coverage determinations often are influenced by current standards of practice and clinical data, particularly at the local level. The Centers for Medicare & Medicaid Services (CMS) which is the government agency responsible for overseeing the Medicare program, has the authority to make coverage determinations on a national basis, but most Medicare coverage decisions are made at the local level by contractors that administer the Medicare program in specified geographic areas. Private and government third-party payors have separate processes for making coverage determinations, and private third-party payors may or may not follow Medicare's coverage decisions. If a third-party payor has a coverage determination in place for a particular diagnostic test, billing for that test must comply with the established policy. Otherwise, the third-party payor makes reimbursement decisions on a case-by-case basis.

Payment. Payment for covered diagnostic tests is determined based on various methodologies, including prospective payment systems and fee schedules. In addition, private third-party payors may negotiate contractual rates with participating providers or set rates as a percentage of the billed charge. Diagnostic tests furnished to Medicare inpatients generally are included in the bundled payment made to the hospital under Medicare's Inpatient Prospective Payment System, utilizing Diagnosis Related Groups (DRGs) depending on the patient’s condition. Payment for diagnostic tests furnished to Medicare beneficiaries in outpatient circumstances is made based on the Clinical Laboratory Fee Schedule, under which a payment amount is assigned to each covered CPT code, or through the Outpatient Prospective Payment System (OPPS), which is the outpatient equivalent of the DRG model. The law technically requires fee schedule amounts to be adjusted annually by the percentage increase in the consumer price index (CPI) for the prior year, but Congress has frozen payment rates in certain years. Medicaid programs generally pay for diagnostic tests based on a fee schedule, but reimbursement varies by state.

European Union

In the European Union the reimbursement mechanisms used by private and public health insurers vary by country. For the public systems reimbursement is determined by guidelines established by the legislator or responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the healthcare system. Acceptance for reimbursement comes with cost, use and often volume restrictions, which again can vary by country.

Conflict Minerals

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 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 conduct due diligence measures annually to determine the presence of conflict minerals in our products and the source of any such conflict minerals. Because we do not purchase conflict minerals directly from smelters or refineries, we rely on our suppliers to specify to us their

Conflict Minerals sources and declare their conflict minerals status. We disclosed our Conflict Minerals findings to the Securities Exchange Commission for the calendar year ending December 31, 2014 on Form SD on April 1, 2015 and will provide updated disclosure to the Securities Exchange Commission annually.

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. A listing of our significant subsidiaries and their jurisdictions of incorporation is included in Exhibit 8.1 to this Annual Report.

Description of Property

Our production and manufacturing facilities for consumable products are located in Germany, the United States, China, and the United Kingdom. Our facilities for software development are located in the United States, Denmark and India. 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 $97.8 million, $86.6 million and $84.5 million for 2015, 2014 and 2013, 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, Maryland. These facilities operate in accordance with cGMP requirements.

The consumable products manufactured at QIAGEN GmbH in Germany, and QIAGEN Sciences LLC in Maryland, are produced under ISO 9001: 2008, ISO 13485:2013, ISO 13485:2003 CMDCAS. Our certifications form part of our ongoing commitment to provide our customers with high-quality, state-of-the-art sample and assay technologies under our Total Quality Management system.

Our facilities in Hilden, Germany, currently occupy a total of approximately 776,000 square feet, some of which is leased pursuant to separate contracts, the last of which expires in 2018. We purchased additional office and warehouse space of approximately 23,700 square feet in 2015. 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 can accommodate over 500 employees. There is room for future expansion of up to 300,000 square feet of facility space. In 2015, we completed expansion of our research and production facilities in Hilden, Germany and renovations of administrative facilities in Germantown, Maryland.

We lease a facility in Frederick, Maryland comprising a total of 42,000 square feet for manufacturing, warehousing, distribution and research operations. We also lease facilities in Massachusetts with 44,400 square feet in Waltham for GeneReader NGS system development and 39,100 square feet in Beverly for enzyme manufacturing. Our California sites have a total of 33,500 square feet in Redwood City for Bioinformatics and 30,000 square feet in Valencia for Customer Care, Sales and Marketing services. Additionally, we lease smaller facilities in Shenzhen, China and Manchester, United Kingdom for manufacturing, warehousing, distribution and research operations. In 2015, we completed expansion work in Manchester to add additional research and development space. 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 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.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

This section contains a number of forward-looking statements. These statements are based on current management expectations, and actual results may differ materially. Among the factors that could cause actual results to differ from

management's expectations are those described in "Risk Factors" and "Forward-looking and Cautionary Statements" in Item 3 of this Annual Report.

Results of Operations

Overview

We are a leading global provider of Sample to Insight solutions to transform biological materials into valuable molecular insights. QIAGEN sample technologies isolate and process DNA, RNA and proteins from any biological sample, such as blood or tissue. Assay technologies make these biomolecules visible and ready for analysis, such as identifying the DNA of a virus or

a mutation of a gene. Bioinformatics solutions integrate software and cloud-based resources to interpret increasing volumes of biological data and report relevant, actionable insights. Our automation solutions tie these together in seamless and cost-effective molecular testing workflows.

We sell our products - consumables, automated instrumentation systems using those technologies, and bioinformatics to analyze and interpret the data - to four major customer classes:

- Molecular Diagnostics - healthcare providers engaged in 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 - pharmaceutical and biotechnology companies using molecular testing to support drug discovery, translational medicine and clinical development efforts
- 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 130 countries, mainly through subsidiaries in markets we believe have the greatest sales potential in Europe, Asia, the Americas and Australia. We also work with specialized independent distributors and importers. As of December 31, 2015, we employed approximately 4,600 people in more than 35 locations worldwide.

Recent Acquisitions

We have made a number of strategic acquisitions since 2013, targeting innovative technologies to achieve market-leading positions in high-growth areas of molecular diagnostics and research. These transactions have expanded our product offerings and technology platforms, as well as our geographic presence. They include:

- In November 2015, we acquired MO BIO Laboratories, Inc., a privately-held provider of cutting-edge sample technologies for studies of the microbiome and metagenomics, analyzing the impact of microbial diversity on health and the environment. The acquisition adds a complementary portfolio of sample technologies to QIAGEN's universal solutions for next-generation sequencing. MO BIO’s currently marketed kits, based on its proprietary Inhibitor Removal Technology, enable the isolation of pure DNA from challenging samples like soil, water, plants and stool.
- In March 2015, we acquired an innovative technology that enables enrichment and molecular analysis of circulating tumor cells (CTCs) from blood samples from AdnaGen GmbH, a subsidiary of Alere Inc. The acquisition added to QIAGEN’s pipeline of technologies under development for molecular testing through less-invasive liquid biopsies as an alternative to costly and risky tissue biopsies. Other assets acquired include two marketed CE-IVD marked products, AdnaTest BreastCancer and AdnaTest Prostate Cancer, which offer improved treatment monitoring and earlier detection of tumor relapse.
- In December 2014, we acquired the enzyme solutions business of Enzymatics, a U.S. company whose products are used in an estimated 80% of all next-generation sequencing workflows. The comprehensive Enzymatics portfolio complements QIAGEN’s leading offering of universal NGS products, advancing our strategy to drive the adoption of NGS in clinical healthcare.
- In April 2014, we acquired BIOBASE, a provider of expertly curated biological databases, software and services based in Wolfenbu ttel, Germany, further expanding our industry-leading bioinformatics solutions. These integrated solutions provide a complete workflow for handling genomic data from biological sample to valuable molecular insights. The content from BIOBASE includes gold-standard data in the fields of inherited diseases and pharmacogenomics. In July, QIAGEN and BGI Tech Solutions Co. announced a distribution and service relationship for the BIOBASE Human Gene Mutation Database (HGMD) in China, Taiwan, Hong Kong and Macao. QIAGEN also has integrated the BIOBASE content into the Ingenuity Knowledge Base, adding value for customers in interpreting genomic data from next-generation sequencing (NGS).
- In August 2013, we acquired CLC bio, a global leader in bioinformatics software with a focus on next-generation sequencing. CLC bio, a privately-held company based in Aarhus, Denmark, has created the leading commercial data analysis solutions and workbenches for NGS. CLC bio’s leading products are CLC Genomics Workbench, a comprehensive and user-friendly analysis package for analyzing, comparing and visualizing NGS data; CLC Cancer Research Workbench, focusing on genomic analysis for oncology; and CLC Genomics Server, a flexible enterprise-level infrastructure and analysis backbone for NGS data analysis.

- In April 2013, we acquired Ingenuity Systems, Inc., the leading provider of software solutions that efficiently and accurately analyze, interpret and report the biological meaning of genomic data. Ingenuity, a privately-held U.S. company based in California's Silicon Valley, created a market leading, expertly curated knowledge system of biomedical information and analysis solutions for the exploration, interpretation and analysis of complex biological systems. New technologies such as next-generation sequencing (NGS) are now generating more data in a single year

than was created in all prior history, making the analysis and interpretation of this extensive and very complex biological data a critical success factor.

- In February 2015, we announced the spin-off of teams and activities of QIAGEN Marseille S.A. (formerly Ipsogen S.A.), a majority-owned and fully consolidated entity. In the divestiture, QIAGEN Marseille agreed to the sale of all its assets and liabilities, with the exception of its intellectual property portfolio, to a stand-alone company. QIAGEN retained rights to commercialize the ipsogen line of products, including companion diagnostics for blood cancers. As part of this initiative, we made a tender offer to acquire the remaining QIAGEN Marseille shares. As of December 31, 2015, we held 97.22% of the shares in QIAGEN Marseille, and we anticipate that we will obtain full ownership during the first quarter of 2016.

Our financial results include the contributions of our recent acquisitions and the QIAGEN Marseille spin-off from their effective dates, as well as costs related to the transactions and integration 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. Considering the acquisitions made during 2015, we determined that we still operate as one business segment. We 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, 2015, Compared to 2014

Net Sales

In 2015, net sales decreased 5% to $1.28 billion compared to $1.34 billion in 2014, due to about eight percentage points of adverse currency movements. Excluding the effect of adverse currency movements, total growth reflected higher contributions from consumables and related revenues (+3% / 87% of sales) and instruments (+5% / 13% of sales). Excluding the effect of adverse currency movements, about two percentage points of total sales growth came from the acquisitions of the Enzymatics NGS technology and consumables portfolio (acquired in December 2014) and the BIOBASE bioinformatics business (acquired in April 2014), while sales in the rest of the business provided about one percentage point. Late in the fourth quarter of 2015, we completed the acquisition of MO BIO Laboratories Inc., a leader in sample technologies for metagenomics and microbiome analysis, but this had a negligible contribution to net sales in 2015. Excluding the expected impact of sharply lower U.S. sales of HPV tests, which created approximately three percentage points of headwind, as well as the effect of adverse currency movements, net sales rose approximately 6% in 2015.

Geographic regions: Excluding the loss of 15 percentage points of sales growth due to adverse currency movements, the Europe / Middle East / Africa region led the geographic performance, benefiting from gains in Germany and Turkey, as well as improving performances in other countries. The Americas advanced at a faster pace (+7%) when excluding U.S. HPV test sales and when excluding 3 percentage points of adverse currency movements. Asia-Pacific / Japan advanced on gains in China and ongoing robust growth in South Korea while Japan sales declined on macro challenges when excluding 8 percentage points of adverse currency movements. Turkey, China, South Korea and India led results for the top emerging markets (+8% / 15% of sales) against declining sales in Mexico and Russia when excluding adverse currency movements of 10 percentage points.

Customer classes: An overview of performance in QIAGEN's four customer classes:

Molecular Diagnostics, which contributed approximately 50% of net sales, declined 7% in 2015 reflecting adverse currency movements of eight percentage points of sales growth in 2015. The core portfolio delivered approximately 7% growth before adverse currency impacts and the ongoing decline in sales of U.S. HPV test products (-43% / 3% of sales). Sales of consumables used on the QIAsymphony automation platform also grew at a solid pace for the full year, as QIAGEN achieved its goal for new QIAsymphony placements, but revenues were negatively impacted by multi-year reagent rental agreements. Personalized Healthcare sales also grew at a higher-single-digit rate for the year.

Applied Testing represented approximately 9% of net sales, declined 1% in 2015 compared to 2014 with adverse currency movements resulting in a loss of eight percentage points of sales growth. Before negative currency impacts, Applied Testing maintained a higher-single-digit growth pace for consumables and related revenues during 2015, while instruments grew at a lower-single-digit rate in the fourth quarter and for the year. All regions showed gains, in

particular for products used in human ID / forensics.

Pharma sales growth remained unchanged compared to 2014 and provided approximately 19% of sales with adverse currency movements resulting in a loss of six percentage points of sales growth. Before negative currency impacts, Pharma advanced on mid-single-digit growth for both instruments and consumables and related revenues in 2015. The Europe / Middle East / Africa region and the Americas offset lower sales in Asia-Pacific / Japan.

Academia represented approximately 22% of net sales and declined 4% in 2015 compared to 2014 with adverse currency movements resulting in a loss of ten percentage points of sales growth. Academia advanced on higher-single digit growth rates for instruments while consumables and related revenues grew at a mid-single digit rate during the course of the year before negative currency impacts. The Americas led growth among all regions and benefited from more positive customer funding trends.

Gross Profit

Gross profit was $826.4 million, or 65% of net sales, in 2015, compared with $864.9 million, or 64% of net sales, in 2014. Adverse currency movements negatively impacted gross profit in 2015 by $71.9 million. Generally, our consumable and related 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. Further, amortization expense related to developed technology and patent and license rights, which have been acquired in business combinations, is included in cost of sales. Gross profit in 2014 was impacted by charges of $26.4 million recorded in cost of sales in connection with internal restructuring efforts as well as those related to acquisitions. In 2014, these charges included $24.2 million in impairments and $2.2 million in contract termination costs as discussed in Note 6 in the accompanying consolidated financial statements.

Cost of sales includes amortization expense related to developed technology and patent and license rights acquired in business combinations. The amortization expense on acquisition-related intangibles within cost of sales increased slightly to $84.5 million in 2015 from $81.7 million in 2014. Acquisition-related intangible amortization would increase in the future should we make further acquisitions.

Research and Development

Research and development expenses decreased by 10% to $147.2 million (11% of net sales) in 2015, compared to $163.6 million (12% of net sales) in 2014. The decrease in research and development expenses is primarily due to $14.3 million of favorable currency exchange impacts. During 2015, we introduced our GeneReader NGS System and will continue to invest in research and development as we are developing a range of upgrades and enhancements to address new applications and market segments. We also plan to introduce additional cancer-related gene panels, with longer-term expansion of the NGS content menu beyond oncology. Further, business combinations, along with the acquisition of new technologies, may increase our research and development costs in the future. 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. 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 instruments. 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 decreased 4% to $361.0 million (28% of net sales) in 2015 from $376.9 million (28% of net sales) in 2014. The decrease was driven by $33.5 million of favorable currency exchange impact which more than offset costs resulting from increased sales and marketing activities. Sales and marketing expenses are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses, United States medical device excise tax (which has been suspended for 2016 and 2017) and other promotional expenses. During 2015, we continued investments in our commercialization activities related to our sales force and e-commerce initiatives which more than offset the favorable currency impacts and lower compensation costs following a reassessment of stock units with performance criteria. We anticipate that sales and marketing costs will increase along with new product introductions and growth in sales of our products.

General and Administrative, Restructuring, Integration and Other

General and administrative, business integration, restructuring and related costs decreased by 18% to $103.9 million (8% of net sales) in 2015 from $126.6 million (9% of net sales) in 2014. The comparison was affected by $8.3 million in restructuring costs in 2014 related to internal restructuring of subsidiaries, including severance and retention costs

as discussed in Note 6 in the accompanying consolidated financial statements. The decrease in general and administrative, business integration, restructuring and related costs includes a $9.9 million favorable currency exchange impact. Additionally, share based compensation costs were lower compared to 2014 following a reassessment of stock units with performance criteria. During 2015 and 2014, we incurred acquisition transaction costs of approximately $7.5 million and $2.0 million, respectively primarily in connection with the 2015 acquisitions, including MO BIO Laboratories, and the 2014 acquisitions of Enzymatics and

BIOBASE. As we further integrate the acquired companies and pursue other opportunities to gain efficiencies, we expect to continue to incur additional business integration in 2016. Over time, we believe the integration activities will reduce expenses as we improve efficiency in 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 2015, amortization expense on acquisition-related intangibles within operating expense increased to $38.7 million, compared to $37.1 million in 2014. We expect acquisition-related intangible amortization will increase as a result of our future acquisitions.

Other Income (Expense)

Other expense was $43.2 million in 2015, compared to $42.3 million in 2014. Total other expense, net is primarily the result of interest expense and other expense, partially offset by interest income and impacts of foreign currency transactions. Included in other income (expense), net for the year ended December 31, 2015, is a $7.6 million loss recognized on the repurchase of the $130.5 million loan payable to and warrant agreement with QIAGEN Finance. For the year ended December 31, 2014, a $4.6 million loss recognized on the redemption of the $300 million loan payable to and subscription right with QIAGEN Euro Finance is included. Both transactions are discussed more fully in Note 15 to the consolidated financial statements.

For the year ended December 31, 2015, interest income increased to $4.8 million from $4.0 million in 2014. Interest income includes interest earned on cash, cash equivalents and short term investments, income related to certain interest rate derivatives entered into in 2015 as discussed in Note 13 and other components including the interest portion of operating lease transactions.

Interest expense decreased to $37.4 million in 2015, compared to $39.3 million in 2014. Interest costs primarily relate to debt, discussed in Note 15 in the accompanying notes to the consolidated financial statements. Interest expense decreased primarily as a result of the repayments of the 2006 Notes as discussed in Note 15 to the consolidated financial statements.

For the year ended December 31, 2015, we recorded net losses on foreign currency of $0.5 million compared to net gains of $1.9 million in 2014. These gains and losses are due to foreign currency rate fluctuations.

Provision for Income Taxes

Our effective tax rates differ from The Netherlands statutory tax rate of 25% due in part to our operating subsidiaries being exposed to effective tax rates ranging from zero to more than 40%. Fluctuations in the distribution of pre-tax (loss) income among our operating subsidiaries can lead to fluctuations of the effective tax rate in the consolidated financial statements. In 2015 and 2014, our effective tax rates were 4% and 1%, respectively. In 2014, The Netherlands’ tax expense was favorably impacted by fully tax exempt income related to financing activities which concluded in 2014 and 2015 and accordingly, the related income tax benefit will not impact our effective tax rate beyond 2015. Additionally, in 2015 and 2014, tax expense on foreign operations was favorably impacted by lower income tax rates and partial tax exemptions on foreign income primarily derived from operations in Germany, Singapore, Luxembourg and Switzerland. These foreign tax benefits are due to a combination of favorable tax laws, rules, rulings, and exemptions in these jurisdictions. In particular, we have pre-tax income in Germany which is statutorily exempt from trade tax on intercompany foreign royalty income. Further, we have intercompany financing arrangements through Luxembourg in which the intercompany income is partially exempt. See Note 16 to the consolidated financial statements for a full reconciliation of the effective tax rate to The Netherlands statutory rate. In future periods, our effective tax rate may fluctuate from similar or other factors as discussed in “Changes in tax laws or their application could adversely affect our results of operations or financial flexibility” in Item 3 Risk Factors.

Year Ended December 31, 2014, Compared to 2013

Net Sales

In 2014, net sales increased 3% to $1.34 billion compared to $1.30 billion in 2013, driven by consumables and related revenues (+3%, 87% of sales) and instruments (+6%, 13% of sales) as well as ongoing business expansion in all

customer classes. About one percentage point of growth came from acquisitions to create industry leadership in bioinformatics with Ingenuity, CLC bio and BIOBASE, and two percentage points from the rest of the business. Currency movements had an adverse impact of one percentage point.

The Europe / Middle East / Africa region (+8% / 34% of sales) had solid growth in Germany, France, United Kingdom and Turkey while also benefiting from ongoing expansion in the Nordic region. The Americas (-1% / 46% of sales) reflected the

anticipated decline in U.S. HPV product sales. The Asia-Pacific / Japan region (+5% / 19% of sales) advanced on high-single-digit growth in China along with gains in Japan and South Korea. Sales in the top seven emerging markets (+2% / 14% of sales) showed gains in China, South Korea and Turkey, which more than offset sharply lower sales in Russia, as well as lower sales in Mexico due to the timing of national tenders.

Molecular Diagnostics, which represents approximately 50% of net sales, expanded by 3% in 2014 advanced on the ongoing solid expansion of QIAGEN's growth drivers, helping to deliver 15% growth in 2014 from the diagnostics portfolio other than U.S. HPV tests and overcoming the full-year decline in U.S. HPV sales (-40%, 6% of total sales). Instrument sales grew at a double-digit pace, supported by ongoing strong placements of the QIAsymphony system. Full-year double-digit sales gains were also delivered by the QuantiFERON-TB test, the Personalized Healthcare portfolio (including higher pharma co-development project revenues compared to 2013) and Profiling consumables.

Applied Testing, which represents approximately 8% of net sales, achieved 8% growth in 2014 compared to 2013, delivered a strong performance in the fourth quarter of 2014, leading to a double-digit sales increase for the full year in instruments and a solid single-digit rise in consumables sales on the back of growth in Human ID / forensics and veterinary applications, as well as the addition of the bioinformatics portfolio.

Pharma, which represents approximately 19% of net sales, rose 4% in 2014 compared to 2013, and saw improving demand in the Americas during 2014, with single-digit increases both in instrument sales and in contributions from consumables and bioinformatics.

Academia, which represents approximately 22% of net sales, increased a modest 1% in 2014, delivered growth for the full year despite challenging funding conditions in the U.S. and other key markets, aided by a return to growth in instrument sales during the fourth quarter as well as higher contributions from consumables sales.

Gross Profit

Gross profit was $864.9 million, or 64% of net sales, in 2014, up from $815.5 million, or 63% of net sales, in 2013. Consumable products (including sample and assay kits as well as bioinformatics solutions) have a higher gross margin than our instruments and service arrangements. Fluctuations in the sales levels of these products and services will have an impact on the gross margin between periods. Gross profit in 2014 and 2013, was impacted by charges of $26.4 million and $40.6 million, respectively, recorded in cost of sales in connection with internal restructuring efforts as well as those related to acquisitions. In 2014, these charges included $24.2 million in impairments and $2.2 million in contract termination costs. In 2013, these charges included $25.2 million in impairments, $6.5 million for contract termination costs, $5.1 million for the write-off of inventory, and $3.5 million for personnel costs.

Cost of sales includes amortization expense related to developed technology and patent and license rights acquired in a business combination. The amortization expense on acquisition-related intangibles within cost of sales increased slightly to $81.7 million in 2014 from $77.9 million in 2013.

Research and Development

Research and development expenses increased by 12% to $163.6 million (12% of net sales) in 2014, compared to $146.1 million (11% of net sales) in 2013. Research and development expenses were minimally affected by currency exchange impacts in 2014. The increase in research and development expenses in 2014 primarily reflects our acquisitions of Ingenuity, CLC bio and BIOBASE; regulatory activity in support of new products; and initiatives in markets such as bioinformatics and next-generation sequencing.

Sales and Marketing

Sales and marketing expenses increased 1% to $376.9 million (28% of net sales) in 2014 from $371.5 million (29% of net sales) in 2013. Sales and marketing expenses are primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses, medical device excise tax and other promotional expenses. The increase in sales and marketing expenses primarily reflects the acquisitions in 2014. The increase was partially offset by $5.1 million of favorable currency exchange impact in 2014.

General and Administrative, Restructuring, Integration and Other

General and administrative, business integration, restructuring and related costs decreased by 36% to $126.6 million (9% of net sales) in 2014 from $199.1 million (15% of net sales) in 2013. The comparison was affected by $78.1 million in restructuring costs in 2013 related to internal restructuring of subsidiaries, including severance and retention costs, plus increased costs in connection with acquisitions, partially offset by operational efficiencies. This includes fixed and intangible asset impairment charges of $11.8 million primarily due to the discontinuation of development

programs. The restructuring costs in 2013 primarily related to a project we began in late 2011 to enhance productivity by streamlining the organization and reallocating resources to strategic initiatives to help drive growth and innovation, strengthen our industry leadership position and improve

longer-term profitability. In connection with the integration of the acquired companies, we aim to improve efficiency in general and administrative operations. Additionally, general and administrative, integration and related costs were favorably impacted by $1.3 million in currency impacts in 2014, compared to the same period of 2013. During 2014, we incurred acquisition transaction costs of approximately $2.0 million, primarily in connection with the acquisition of Enzymatics and BIOBASE. During 2013, we incurred acquisition transaction costs of approximately $2.0 million, primarily in connection with the acquisitions of Ingenuity and CLC bio.

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 2014, amortization expense on acquisition-related intangibles within operating expense increased to $37.1 million, compared to $35.5 million in 2013.

Other Income (Expense)

Other expense was $42.3 million in 2014, compared to $26.0 million in 2013. Total other expense, net is primarily the result of interest expense and losses on foreign currency transactions partially offset by interest income and gains on foreign currency transactions. Additionally, for the year ended December 31, 2014, we recorded an impairment of $4.8 million to a cost method investment in other expense, net. Also, included in other expense, net is a $4.6 million loss recognized on the redemption of the $300 million loan payable to and subscription right with QIAGEN Euro Finance as discussed more fully in Note 15 to the consolidated financial statements, "Lines of Credit and Debt."

For the year ended December 31, 2014, interest income increased to $4.0 million from $2.3 million in 2013. Interest income primarily reflects the changes in our cash and short-term investments and the changing interest rates thereon.

Interest expense increased to $39.3 million in 2014, compared to $30.9 million in 2013. Interest costs primarily relate to debt, discussed in Note 15 in the accompanying notes to the consolidated financial statements. Interest expense increased primarily as a result of the issuance of the Cash Convertible Notes in March 2014, partially offset by the repayment of the $300.0 million 2006 Notes during March 2014 as discussed in Note 15 to the consolidated financial statements.

For the year ended December 31, 2014, foreign currency gains of $1.9 million were realized compared to a gain of $5.6 million in 2013.

Provision for Income Taxes

Our effective tax rates differ from The Netherlands statutory tax rate of 25% due in part to our operating subsidiaries being exposed to effective tax rates ranging from zero to more than 40%. Fluctuations in the distribution of pre-tax (loss) income among our operating subsidiaries can lead to fluctuations of the effective tax rate in the consolidated financial statements. In 2014 and 2013, our effective tax rates were 1% and -85%, respectively. Income tax expense increased in 2014 compared to 2013, mainly reflecting improved operating results. In 2014 and 2013, The Netherlands’ tax expense was favorably impacted by fully tax exempt income related to financing activities which concluded in 2014 and 2015. Additionally, in 2014 and 2013, tax expense on foreign operations was favorably impacted by lower income tax rates and partial tax exemptions on foreign income primarily derived from operations in Germany, Singapore, Luxembourg and Switzerland. These foreign tax benefits are due to a combination of favorable tax laws, rules, rulings, and exemptions in these jurisdictions. In particular, we have pretax income in Germany which is statutorily exempt from trade tax on intercompany foreign royalty income. Further, we have intercompany financing arrangements through Luxembourg in which the intercompany income is partially exempt. In addition to these impacts in 2014 and 2013, in certain foreign jurisdictions, primarily Germany and the United States, we recorded acquisition related and impairment charges which reduced pretax income in higher tax jurisdictions. See Note 16 to the consolidated financial statements for a full reconciliation of the effective tax rate to The Netherlands statutory rate.

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 2015, 2014 and 2013 was $(0.5) million, $1.9 million, and $5.6 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 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 speculative purposes. We recognize all derivatives as either assets or liabilities on the balance sheet, 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. In determining fair value, we consider both the counterparty credit risk and our own creditworthiness. We have agreed with almost all of our counterparties with whom we enter into cross-currency swaps, interest rate swaps or foreign exchange contracts, to enter into bilateral collateralization contracts under which we receive or provide cash collateral, as the case may be, for the net position with each of these counterparties, which effectively eliminates credit risk.

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 and option contracts as well as cross-currency swaps.

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

Further details of our derivative and hedging activities can be found in Note 13 to the accompanying consolidated 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 investing activities including capital expenditure requirements and acquisitions. As of December 31, 2015 and 2014, we had cash and cash equivalents of $290.0 million and $392.7 million, respectively. We also had short-term investments of $130.8 million at December 31, 2015. 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, 2015, cash and cash equivalents had decreased by $102.7 million from December 31, 2014, primarily as a result of cash used in financing activities of $258.6 million and cash used in investing activities of $146.2 million, partially offset by cash provided by operating activities of $317.5 million. As of December 31, 2015 and 2014, we had working capital of $693.3 million and $717.1 million, respectively.

Operating Activities. For the years ended December 31, 2015 and 2014, we generated net cash from operating activities of $317.5 million and $288.0 million, respectively. While net income was $126.9 million in 2015, non-cash components in income included $191.5 million of depreciation and amortization. Operating cash flows include a net decrease in working capital of $23.6 million excluding changes in fair value of derivative instruments. The current period change in working capital is primarily due to increased accounts receivables and inventories and decreased accrued liabilities, partially offset by cash payments collected from derivative contracts. 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 $146.2 million of cash was used in investing activities during 2015, compared to $407.6 million during 2014. Investing activities during 2015 consisted principally of $317.6 million for purchases of short-term investments, fully offset by $367.7 million from the sale of short-term investments, $97.8 million in cash paid for purchases of property and equipment, including our construction projects in the U.S and software development costs, as well as $19.7 million paid for intangible assets. Cash paid for acquisitions, net of cash acquired, of $66.9 million represents the total cash paid for three acquisitions, including the acquisition of MO BIO Laboratories. As of December 31, 2015, we also had made strategic investments of $6.1 million in privately held companies as discussed in Note 10.

In connection with certain acquisitions, we could be required to make additional contingent cash payments totaling up to $67.8 million based on the achievement of certain revenue and operating results milestones as follows: $40.2

million in 2016, $15.5 million in 2017, $5.1 million in 2019, and $7.0 million, payable in any 12-month period from now until 2029 based on the accomplishment of certain revenue targets. Of the $67.8 million total contingent obligation, we have assessed the fair value at December 31, 2015, to be $17.7 million, of which of which $10.7 million is included in other long-term liabilities and $7.0 million is included in accrued liabilities in the accompanying balance sheet as of December 31, 2015.

Financing Activities. Approximately $258.6 million of cash was used in financing activities for the year ended December 31, 2015 compared to cash provided by financing activities of $192.8 million in 2014. Cash used during 2015, was mainly due to the repayment of the long-term debt of QIAGEN Finance of $250.9 million as discussed in Note 15 "Lines of Credit and Debt." In 2014, the net proceeds from the issuance of the Cash Convertible Notes and the Warrants, net of the cost of the purchased

Call Options, were substantially used to fund the redemption of the 2006 Notes and related subscription right also discussed in Note 15. Additionally, cash used during 2015 included $20.8 million for the purchase of treasury shares which was partially offset by $10.3 million for the issuance of common shares in connection with our stock plan.
In October 2015, we extended the maturity of our €400 million syndicated revolving credit facility, which now has a contractual lifetime until December 2020 of which no amounts were utilized at December 31, 2015. The facility can be utilized in euro, British pounds sterling or U.S. dollar and bears interest of 0.40% to 1.20% 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. We have additional credit lines totaling €36.6 million with no expiration date, none of which were utilized as of December 31, 2015. We also have capital lease obligations, including interest, in the aggregate amount of $4.0 million, and carry $1.1 billion of long-term debt, of which no amounts are current as of December 31, 2015.
In March 2014, we issued $730.0 million aggregate principal amount of Cash Convertible Senior Notes of which $430.0 million is due in 2019 (2019 Notes) and $300.0 million is due in 2021 (2021 Notes). We refer to the 2019 Notes and the 2021 Notes, collectively as the “Cash Convertible Notes” which are discussed fully in Note 15 to the consolidated financial statements. Interest on the Cash Convertible Notes is payable semiannually in arrears on March 19 and September 19 of each year, at rates of 0.375% and 0.875% per annum for the 2019 Notes and 2021 Notes, respectively, commencing on September 19, 2014. The 2019 Notes will mature on March 19, 2019 and the 2021 Notes will mature on March 19, 2021, unless repurchased or converted in accordance with their terms prior to such date.
We had notes payable, which were 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). The 2004 Notes were convertible into our common shares at a conversion price of $12.6449, subject to adjustment. In connection with conversions of $14.9 million of the 2004 Notes, we previously repaid $14.5 million of the debt to QIAGEN Finance. During 2015, we paid $250.9 million for the redemption of the remaining loan and repurchased the warrant agreement with QIAGEN Finance and recognized a loss of $7.6 million in other (expense) income, net.
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.
In 2012, our Supervisory Board approved a program authorizing management to purchase up to a total of $100 million of our common shares (excluding transaction costs).We completed this share repurchase program in April 2013 having repurchased, between October 2012 and April 2013, a total of 5.1 million QIAGEN shares for an aggregate cost of $99.0 million.
In 2013, we announced a second share buyback program, to purchase up to another $100 million of our Common Shares (excluding transaction costs). We completed the share repurchase program in June 2014 having repurchased between September 2013 and June 2014 a total of approximately 4.4 million QIAGEN shares for a total aggregate cost of $100.4 million (including performance fees).
In July 2014, we announced the launch of our third $100 million share repurchase program to purchase up to another $100 million of our common shares (excluding transaction costs). In 2014, 2.1 million QIAGEN shares were repurchased for $49.1 million (excluding transaction costs) and in 2015 0.8 million QIAGEN shares were repurchased for $20.8 million. This program expired in December 2015. Repurchased shares will be held in treasury in order to satisfy obligations for exchangeable debt instruments and employee share-based remuneration plans.
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, any 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. 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 former arrangements with QIAGEN Finance and QIAGEN Euro Finance as discussed in Note 15 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, 2015, 2014 and 2013.

Contractual Obligations

As of December 31, 2015, our future contractual cash obligations are as follows:

Contractual Obligations (in thousands)	Payments Due by Period						
	Total	2016	2017	2018	2019	2020	Thereafter
Long-term debt [1]	$1,172,972	$18,869	$18,869	$18,869	$487,317	$14,928	$614,120
Purchase obligations	99,212	67,609	15,970	8,453	7,044	136	—
Operating leases	54,444	18,166	12,894	8,207	5,878	4,376	4,923
License and royalty payments	7,794	1,333	1,277	1,221	1,151	1,151	1,661
Capital lease obligations [2]	4,024	1,307	1,212	1,505	—	—	—
Total contractual cash obligations	$1,338,446	$107,284	$50,222	$38,255	$501,390	$20,591	$620,704

(1) Amounts include required principal, stated at current carrying values, and interest payments.

(2) Includes future cash payments, including interest, due under capital lease arrangements.

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 $67.8 million based on the achievement of certain revenue and operating results milestones as follows: $40.2 million in 2016, $15.5 million in 2017, $5.1 million in 2019 and $7.0 million, payable in any 12-month period from now until 2029 based on the accomplishment of certain revenue targets, the launch of certain products or the grant of certain patent rights. As of December 31, 2015, we have accrued $17.7 million.

Liabilities associated with uncertain tax positions, including interest and penalties, are currently estimated at $18.1 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.

Critical Accounting Policies, Judgments and Estimates

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

Revenue Recognition. We recognize revenue 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. Determination of criteria (3) and (4) could require management's judgments

regarding the fixed nature of the fee charged for services rendered and products delivered and the collectability of those fees. While the majority of our sales agreements contain standard terms and conditions, we do enter into agreements that contain multiple elements or non-standard terms and conditions. Sometimes interpretation of the sales agreement or contract for multiple-element arrangements is complex in determining whether there is more than one unit of accounting and if so, how and when revenue should be