MANAGEMENT REPORT

Business and Operating Environment

QIAGEN is a global leader in Sample to Insight solutions that transform biological samples into valuable molecular insights. Our mission is to enable our customers in four broad classes - Molecular Diagnostics, Applied Testing, Pharma and Academia - to achieve outstanding success and breakthroughs, all in keeping with our goal of making improvements in life possible.

QIAGEN's solutions integrate sample and assay technologies, bioinformatics and automation systems into workflows that help customers move from Sample to Insight. Our solutions support more than 500,000 customers worldwide in generating insights into the molecular building blocks of life. Our proven solutions are providing answers in hospitals and laboratories worldwide, helping make sense of the increasing volumes and complexity of biological information.

As we move deeper into "the Century of Biology," knowledge of the molecular basis of life has been growing exponentially, along with greater understanding of diseases and biological mechanisms. Dramatic acceleration in the speed of analyzing DNA - and reduction in cost - is generating new discoveries and vast quantities of genomic data. This revolution in the life sciences is transforming healthcare and influencing many other areas of everyday life. QIAGEN's mission is to make improvements in life possible by providing innovative technologies to enable this ongoing wave of discovery and its wide-ranging applications.

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. We believe 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 accessible for analysis, such as identifying the genetic information of a pathogen or a gene mutation in a tumor. QIAGEN's industry-leading bioinformatics solutions allows users to analyze and interpret data to provide relevant, actionable insights. Our automation systems for polymerase chain reaction (PCR), next-generation sequencing (NGS) and other technologies tie these together in seamless and cost-effective molecular testing workflows - from Sample to Insight.

Net sales of $1.42 billion in 2017 consisted of consumable kits and other revenues (88% of sales) and automation systems and instruments (12% of sales). Approximately 48% of net sales in 2017 were in Molecular Diagnostics, and 52% in Life Sciences customer classes in the Academia, Pharma and Applied Testing markets.

QIAGEN has grown substantially by developing new platforms, consumables and bioinformatics to meet growing needs in the market, partnering with researchers and Pharma companies, and acquiring companies or technologies to complement our portfolio. We believe the addressable global market for QIAGEN's portfolio of molecular testing products for customers across the continuum of life science research and molecular diagnostics totals more than $8 billion.

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 New York Stock 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.

Operating Environment in 2017

Economic Environment

A broad global upswing delivered stronger-than-expected economic growth in 2017, creating opportunities for QIAGEN, despite some uncertainties in the business and political environment. Real Gross Domestic Product (GDP) for the world grew approximately 3.0% in 2017, up from 2.4% in 2016 and 2.8% in 2015, according to World Bank estimates. More than half of the world's economies accelerated in 2017: The United States and Europe stepped up growth from slow to moderate, while emerging markets such as China, India and Turkey grew much faster than average. Macroeconomic influences included continued low financing costs, growth-oriented fiscal and monetary policies, strong investment driven by business confidence, and a recovery in commodity prices. The U.S. dollar declined against other major currencies in 2017, but had little overall effect on QIAGEN results, reported in dollars.

Industry Environment

As genomic knowledge expands, molecular testing is unlocking valuable insights to meet an increasing range of needs in healthcare, academic research, pharmaceutical R&D and public safety. The secular growth trend in sales of instruments, reagents and other consumables, and bioinformatics solutions continued in 2017. Technologies for next-generation sequencing (NGS) and polymerase chain reaction (PCR) continued to disseminate worldwide. Molecular diagnostics is the most dynamically growing segment of in vitro diagnostics, enabling clinicians to identify and profile cancers, infectious diseases, prenatal or neonatal health threats, and patients' immune status. Regulatory and reimbursement climates continue to evolve. In 2017, precision medicine advanced with the first FDA approvals of cancer drugs targeted by biomarker testing rather than tumor sites, and immuno-oncology drugs using gene editing to mobilize patients' immune cells. In Academia, spending on NGS and other molecular technologies grew on improving customer sentiment, despite concerns about research funding. The Pharma industry increasingly guides drug discovery and development with advanced molecular testing, although R&D spending by individual companies depends on company-specific issues. Applied Testing also continues to grow, led by human identification and forensics. The migration of genomic technologies from basic research into the mainstream is a powerful driver for long-term growth of the industry, increasing the need for scalable, user-friendly and efficient workflows from beginning to end in molecular testing.

Recent Developments

QIAGEN has recently achieved a number of strategic milestones by continuing to focus on strategic growth initiatives:

QuantiFERON-TB franchise growing rapidly:

- QIAGEN is aiding the global fight against tuberculosis (TB), a contagious bacterial infection that strikes more than 10 million new persons and kills about 1.8 million annually. The global epidemic is complicated because an estimated one out of three people have latent TB infection, a phase in which the bacterium infects a person but produces no detectable symptoms. About 5-10% of those individuals, if untreated, will progress to the active TB disease, so screening of high-risk individuals and treatment for latent TB plays an important role in global tuberculosis control efforts.
- QIAGEN's novel QuantiFERON tests, the fourth-generation QuantiFERON-TB Gold Plus (QFT-Plus) and third-generation QuantiFERON-TB Gold (QFT), are the market-leading modern diagnostic tools for latent TB infection. In a class known as interferon-gamma release assays (IGRAs), QuantiFERON-TB tests have been shown in clinical studies to be faster, less labor-intensive and more accurate than the century-old tuberculin skin test. QFT is one of two tests mentioned in the World Health Organization guidelines as an alternative to tuberculin skin tests. First introduced in 2015, QFT-Plus adds clinical insights with antigens that measure the cell-mediated immune response to TB infection from both CD4+ and CD8+ T cells. The addition of CD8+ assessment led WHO in its Global TB Report 2016 to cite QFT-Plus (the only such test on the market) for its potential in identifying at-risk adults at greater risk of progressing to active TB. QFT-Plus is now available in more than 75 countries in Europe, the Americas, Africa, Asia and Middle East. The laboratory-based QuantiFERON-TB tests are displacing the more subjective and time-consuming tuberculin skin test, and sales surpassed $175 million in 2017.
- In October 2017 QIAGEN launched QuantiFERON-TB Gold Plus in the United States after it received Food and Drug Administration approval. Japan also recently approved QFT-Plus. These market introductions follow adoption of QFT-Plus in more than 75 countries across Europe, the Middle East, Africa, Asia and Latin America, where nearly two million of the tests have been used. QFT-Plus advances the science of TB testing with innovative antigens that measure each patient's cell-mediated immune response from both CD4+ and CD8+ T cells, a unique capability. An increasing number of peer-reviewed publications support the efficacy of QFT-Plus, which is the only interferon-gamma release assay (IGRA) test on the pathway to evaluation by the World Health Organization (WHO) for its global campaign to eradicate TB.
- In January 2018, QIAGEN began a new partnership with DiaSorin that will provide a state-of-the-art automation option for QuantiFERON-TB Gold Plus customers, embedding QFT-Plus in a broad and highly synergistic assay menu for DiaSorin's LIAISON-family analyzers. More than 7,000 LIAISON-family analyzers are already in use worldwide.

Next-generation sequencing solutions extending QIAGEN's reach:

- As a leader in "universal" technologies for use with any next-generation sequencing system, as well as creator of the innovative GeneReader NGS System for benchtop sequencing, QIAGEN continues to expand its presence in the rapidly growing market for NGS solutions in laboratories around the world. QIAGEN's NGS portfolio produced more than $115 million in sales in 2017.
- In 2017 QIAGEN continued to broaden its portfolio of platform-agnostic NGS solutions, streamlining tasks such as automated sample and library preparation, reliable detection of DNA and RNA variations, and bioinformatics for analysis and interpretation. Our industry-leading solutions for preparation of liquid biopsy samples, along with a diverse offering of off-the-shelf and customized QIAseq panels, continued to expand to new applications.

QIAGEN's GeneReader NGS System, the first complete Sample to Insight next-generation sequencing solution designed for any laboratory to deliver actionable results, continued to gain acceptance with strong growth in placements in 2017.

- We expanded the GeneReader system's capabilities and content menu for clinical researchers in 2017. Going beyond the original GeneRead QIAact Actionable Insights Tumor Panel (AIT), we launched the GeneRead QIAact Lung DNA Panel and Lung RNA Panel for deep analysis of lung cancer samples and the GeneRead QIAact BRCA 1/2 Panel for in-depth insights into breast and ovarian cancers. All of the QIAact NGS panels run with the GeneReader system and integrate seamlessly with our QCI bioinformatics software for analysis and interpretation.

We have incorporated the GeneReader NGS System into collaborations with pharmaceutical companies for co-development of companion diagnostics.

- Multiple studies demonstrating the efficacy of QIAGEN's GeneReader system, panels and other NGS solutions were presented in major scientific meetings in 2017, including the American Society of Clinical Oncology (ASCO), American Society of Human Genetics (ASHG) and Association for Molecular Pathology (AMP). At the AMP annual meeting in November 2017, about 10 percent of the more than 500 papers presented relied on QIAGEN solutions for some aspect of molecular testing, from sample technologies for NGS to bioinformatics for interpretation of data.
- To accelerate the growth of the GeneReader system in China, QIAGEN formed a joint venture in 2017 with Maccura, a leading in vitro diagnostics company in China. The venture, MAQGEN Biotechnology Co., Ltd. (MAQGEN), will develop local adaptations, pursue regulatory paths to maximize the GeneReader's value and leverage Maccura's broad customer network to expand adoption in laboratories across China. The NGS market in China is growing rapidly in personalized medicine and clinical research. MAQGEN China is 60% owned by Maccura and 40% by QIAGEN.
- In late 2017, QIAGEN created a new unit, Enterprise Genomics Services, to serve the growing demand for customization of NGS gene panels with integrated bioinformatics for dedicated applications. This initiative offers benefits to customers in implementation time, expense and risk mitigation across the continuum from NGS discovery to panel development, optimization, verification and implementation. QIAGEN's capabilities support customized solutions for any NGS platform, including the GeneReader NGS System.
- In Applied Testing, QIAGEN collaborated with the International Commission on Missing Persons (ICMP) in 2017 to launch a cutting-edge next-generation sequencing workflow for DNA identification at the ICMP's laboratory in The Hague. The lab integrates the GeneReader system, other QIAGEN instruments and a new NGS panel specifically designed to identify missing persons. QIAGEN will supply software, reagents, consumables and technical support on an ongoing basis.

Continued Leadership in Personalized Healthcare:

- QIAGEN strengthened its leading position in Personalized Healthcare in 2017, surpassing a milestone of 25 master collaboration agreements with pharma and biotech companies to develop companion and complementary diagnostics providing individualized genomic insights to guide clinical decision-making. QIAGEN launched 15 new companion diagnostic projects in 2017, a record high for QIAGEN. In addition, we continued to achieve regulatory approvals of companion diagnostics and to launch them commercially.
- A major initiative in 2017 was QIAGEN's expansion into developing biomarker tests to support emerging therapies in immuno-oncology (I-O), a novel approach using drugs to target the body's immune system to help fight cancer. QIAGEN and Bristol-Myers Squibb launched a groundbreaking collaboration to explore the use of NGS technology to develop gene expression profiles (GEPs) as predictive or prognostic tools for use with a number of novel immuno-oncology molecules Bristol-Myers Squibb is developing. QIAGEN subsequently has entered into other agreements with undisclosed industry partners to co-develop molecular tests to identify patients who could benefit from I-O therapies. QIAGEN obtained a worldwide license in 2017 from The Johns Hopkins University for biomarkers that play roles in identifying patients for I-O therapies.
- QIAGEN continues to roll out regulator-approved companion diagnostics that deliver actionable insights for treatment decisions based on patients' genomic information. We launched the ipsogen JAK2 RGQ PCR Kit in 2017 as the only FDA-cleared JAK2 kit for blood cancers, diagnosing gene mutations in patients with Polycythemia Vera. The FDA approval was expanded in early 2018 to other myeloproliferative neoplasms. The FDA indicated use of QIAGEN's therascreen EGFR RGQ PCR Kit as a companion diagnostic also was expanded in early 2018 to diagnose additional EGFR gene mutations involved in treatment decisions for first-line treatment of metastatic non-small cell lung cancer (NSCLC).

- We added a new liquid biopsy assay in 2017 for clinical research - the AdnaTest Prostate Cancer Panel AR-V7, using circulating tumor cells to monitor RNA expression of a biomarker indicating resistance to prostate cancer treatments.
- As one of the world's leading independent developers of molecular technologies, with a diverse portfolio of sequencing platforms and solutions, QIAGEN is a preferred industry partner for developing companion or complementary diagnostics.

QIAsymphony delivering platform growth as content menu expands:

- QIAGEN surpassed its 2017 goal of 2,000 cumulative placements of QIAsymphony, a cost-effective modular system that integrates PCR molecular testing workflows from initial biological sample processing to final insights. The platform's rapid dissemination and growing content menu fueled double-digit growth in consumables for QIAsymphony.
- The QIAsymphony automation system serves laboratories around the world, with the broadest test menu of any platform in its category in Europe and other markets, plus the unique ability to handle laboratory-developed tests. Nearly 30 diagnostic tests in infectious disease, oncology and transplant care are marketed for use on the Rotor-Gene® Q, a component of the modular QIAsymphony workflow. In the United States, eight FDA-approved diagnostic tests, including three companion diagnostics to guide treatment decisions in cancer, are marketed for this detection platform.
- Two new QIAGEN test kits were approved by the FDA in 2017 for use on QIAsymphony instruments: the ipsogen JAK2 RGQ PCR Kit, a qualitative test for the detection of an important genetic variant in blood cancers; and the artus CMV QS-RGQ MDx kit, to monitor solid organ transplant patients for cytomegalovirus (CMV), a common infection that can be life-threatening in vulnerable patients.
- The QIAsymphony system's sample processing module, QIAsymphony SP, is a market-leading "front end" automated solution for downstream molecular testing. The growth of next-generation sequencing has highlighted the critical need of laboratories for reliable, automated processing of samples, including liquid biopsies. QIAsymphony SP automates the processing of nucleic acids for analysis with the GeneReader NGS System or other sequencers.

Leadership in differentiated core technologies continuing to drive growth:

- As a world leader in sample technologies enabling laboratories to obtain highest-quality DNA and RNA for molecular testing, QIAGEN continued to expand its offerings in 2017 with differentiated solutions for front-end challenges. QIAGEN technologies process an estimated 50,000 biological samples a day. Our strategic focus is on rapidly growing applications in research and clinical diagnostics, such as handling microbiome samples, where we have an estimated 75% market share.
- Innovation in "liquid biopsy" technologies is increasingly enabling QIAGEN customers to unlock molecular insights from blood or other fluids as non-invasive alternatives to surgical biopsies. Our solutions based on several different technologies for isolation and stabilization of nucleic acids are used in an estimated 80% of liquid biopsy testing.
- Partnering with leading providers of molecular testing services, QIAGEN continues to incorporate its differentiated solutions in liquid biopsy testing. In 2017, for example, QIAGEN's PAXgene® Blood ccfDNA Tube was adopted by Clinical Genomics for sample collection with its assay to monitor patients for recurrence of colorectal cancer.
- To facilitate the growing trend toward liquid biopsies for routine use in clinical testing, QIAGEN joined CANCER-ID, a public-private consortium working to establish standard protocols and clinical validation for blood-based biomarkers in lung and breast cancer. QIAGEN is helping create standardized methods and Sample to Insight workflows.
- QIAGEN launched a Custom Solutions business in 2017 to serve life science and molecular diagnostics customers with the tools and expertise to quickly build and commercialize products that meet unique workflow requirements.

The new unit offers custom and OEM sample technologies, oligo and enzyme product options for PCR, qPCR and NGS product development, as well as a range of other platform technologies.

- In forensics, QIAGEN's long-standing leadership in developing international standards of quality for products to collect and test samples for human identification gained support in 2017 with third-party certification that QIAGEN meets state-of-the-art requirements for forensics supply chain and manufacturing (ISO18385:2016).

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

- QIAGEN's broad offering of content-enabled bioinformatics software continues to grow both as a standalone franchise and as a driver integrated into QIAGEN's Sample to Insight workflows. Our bioinformatics 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. Studies by leading institutions often use solutions such as QIAGEN Clinical Insight (QCI) or CLC Genomics Workbench to analyze and interpret genomic data. QIAGEN pursues collaborations across the genomics and bioinformatics community to offer customers the richest access possible to insights for research and diagnostics.

- In January 2017, QIAGEN acquired OmicSoft Corporation to expand its solutions and enable scientists to visualize and mine large institutional and publicly available "omics" datasets, in addition to the expertly curated, literature-based datasets marketed by QIAGEN. Its OmicSoft solutions meet a growing need in discovery and translational research to access and manage huge amounts of data on DNA, RNA and other sequencing insights.

- In October 2017, QIAGEN partnered with CENTOGENE AG, a leader in testing for rare diseases and hereditary disorders, to provide customers of both companies with more complete insights. QIAGEN integrated CENTOGENE's rare disease variant database into its bioinformatics offerings for genomic interpretation, while CENTOGENE licensed QIAGEN's bioinformatics solutions for use in its diagnostic testing services for rare diseases.

- Advancing the potential of precision medicine for the diagnosis and treatment of cancer, in November 2017 we launched enhancements in our QIAGEN Clinical Insight (QCI) bioinformatics software to automate guidelines published by leading oncology and pathology groups for the use of next-generation sequencing in genetic profiling of cancers. QIAGEN's QCI-Interpret software integrates the consensus AMP/ASCO/CAP standards with our comprehensive biomedical knowledge base to guide the selection of treatments based on findings from each patient's genomic testing and diagnosis.

- Also in November 2017, a collaboration in women's health with Counsyl, a company based in California, demonstrated the value of QIAGEN Clinical Insight for interpretation of results from prenatal testing and hereditary disease screening. Counsyl reported that using QCI for interpreting and scoring genetic variants reduced search time for literature references by 75%, while maintaining accuracy.

Targeted action increasing returns to shareholders:

- In 2017, QIAGEN fulfilled its commitment to return $300 million to shareholders through share repurchase transactions, including the return of $245 million through a synthetic share repurchase in January 2017 and the open-market repurchase of 1.9 million shares on the Frankfurt Stock Exchange for approximately $60 million in September 2017. Reaffirming its commitment to a disciplined approach to capital allocation, QIAGEN announced a new commitment to return $200 million to shareholders beginning in 2018 via open-market repurchases. Shares will be repurchased on the Frankfurt Stock Exchange.

- In 2017, QIAGEN continued to execute previously announced restructuring actions to improve efficiency and profitability, while supporting momentum in sales growth. Key areas include consolidating activities into shared service centers and global centers of excellence, gaining efficiencies in marketing, and embracing digital tools across the business. In 2017, we launched a shared service center for administrative functions in the Philippines, expanding on the efficiencies and complementing the geographic footprint of our first shared service center in Poland. A pre-tax restructuring charge of $19.8 million ($0.06 per share after taxes) was recorded in 2017 for these changes. In addition, following enactment of the new U.S. tax law in December 2017, QIAGEN announced

restructuring initiatives to mitigate some of its impacts, resulting in a pre-tax restructuring charge of $13.8 million ($0.04 per share after taxes) in the fourth quarter. Operating results in 2017 show the benefits in cost reduction and profitability, and targeted actions are continuing into 2018.

- In a review aimed at freeing resources to focus on high-growth market opportunities, QIAGEN took steps in late 2017 to streamline its product portfolio in China, the company's second-largest market, by discontinuing the commercialization of some non-core PCR tests and externalizing the HPV test (cervical cancer screening) franchise to a third-party company in China. A partnership became effective in January 2018 with a Chinese company that has absorbed R&D, commercial distribution, and the related QIAGEN employees and infrastructure of the HPV test franchise in China. QIAGEN has become a minority shareholder of this company. QIAGEN China will focus additional resources on QuantiFERON-TB, the new MAQGEN China joint venture with Maccura for the GeneReader NGS System, and the life sciences portfolio.

Products

QIAGEN's leadership in Sample to Insight solutions for molecular testing leverages our position across a wide range of applications and customer classes. We provide more than 500 core consumable products (sample and assay "kits"), as well as instruments and automation systems. Our bioinformatics solutions connect laboratory workflows and process genomic data, reporting relevant insights to enable scientists or clinicians to decide on further action.

These 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%-80% of net sales, typically include sample technologies to extract and purify molecules of interest from biological samples and assay technologies that make information from these samples available for analysis and interpretation. To maximize customer convenience and reduce user error, these kits contain all necessary reagents and a manual of protocols and background information. Reliability, standardization, ease of use and cost-effectiveness are keys to the success of molecular testing products.

QIAGEN's **sample technologies** ensure that each biological sample is processed in a highly reproducible, standardized method with the highest quality. A broad range of kits support applications such as plasmid DNA purification, RNA purification and stabilization, genomic and viral nucleic acid purification, DNA cleanup after PCR and sequencing, target enrichment, and library preparation for sequencing. We continue to expand our portfolio for applications such as preparing DNA and RNA from minimally-invasive liquid biopsies for cancer and processing difficult samples for research into the microbiome and metagenomics.

Our **assay technologies** contain all the needed reagents to enable customers to target molecules of interest for detection on platforms supporting PCR, NGS or multimodal analysis. Each assay kit is sufficient to support a number of applications, varying from a single application to kits containing more than 1,000 applications each. Applications include open, general-purpose PCR reagents, as well as kits for the detection of viral or bacterial pathogens and parasites, pharmacogenomic testing and genotyping. In PCR, examples are our therascreen family of companion diagnostics, artus line for profiling infectious diseases, and investigator assays for forensics and human identification. A growing portfolio of Digital NGS panels enable sequencing to target DNA or RNA variants for clinical research in cancer or other diseases.

Related revenues, accounting for approximately 7%-8% of our net sales, include **bioinformatics solutions**, sold as freestanding software or cloud-based solutions and also integrated into many QIAGEN consumables and instruments for seamless Sample to Insight workflows. Examples of our bioinformatics solutions:

- **Ingenuity Variant Analysis**, a powerful cloud-based platform tapping into the QIAGEN Knowledge Base, interprets data from NGS analysis to efficiently filter genetic variants and interpret links to diseases.
- **QIAGEN Clinical Insight**, a unique evidence-based decision support solution, draws on the QIAGEN Knowledge Base to deliver clinically relevant insights from complex genomic variants identified in NGS.
- **CLC Genomics Workbench** incorporates cutting-edge technology and algorithms to overcome challenges face by scientists in analyzing and visualizing data from all major NGS platforms.
- **GeneGlobe**, a web-based portal, enables researchers to search and select gene- and pathway-specific solutions from approximately 25 million pre-designed and custom PCR assay kits, NGS panels and other products.

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 approximately 12%-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, and 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. Often several of these instruments are integrated into end-to-end workflows.

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

- **QIAsymphony** is a user-friendly automation system that is driving a new era of integrated workflow, making molecular testing more efficient and helping disseminate standardized, clinically proven molecular diagnostics. The platform includes three modules - **QIAsymphony SP** for sample preparation, **QIAsymphony AS** for assay setup, and **Rotor-Gene Q**, our rotary real-time PCR cycler system, which makes sequences of DNA and RNA visible through amplification and quantifiable. The fully integrated system with all three modules is **QIAsymphony RGQ**. In 2017, our installed base surpassed 2,000 QIAsymphony systems worldwide, serving in a wide variety of laboratories and applications. 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.
- **GeneReader NGS System**, introduced in late 2015, continues to gain acceptance as the first complete Sample to Insight next-generation sequencing (NGS) solution designed for any laboratory to deliver actionable results. This end-to-end platform provides a simpler, more cost-effective way for basic and translational research to take advantage of NGS technology and improve outcomes. The GeneReader workflow 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. In 2017, we continued to enhance performance and added new content, including QIAact panels for deep analysis of lung, breast and ovarian cancers, as well as customized panels for users' specific needs. GeneReader's digital sequencing integrates seamlessly with QIAGEN bioinformatics solutions for interpretation.
- **QIAcube** robotic workstations provide highly versatile solutions for automated sample processing, with novel technologies for purification of DNA, RNA and proteins, saving laboratory staff time and enabling standardized results in analysis using PCR or NGS.

- **QIAxcel** replaces traditional slab-gel analysis, eliminating time-consuming nucleic acid separation methods in low- to high-throughput labs and offering unprecedented sensitivity and time-to-results for analysis of DNA fragments and RNA.
- **QIAgility** is a compact benchtop instrument that enables rapid, high-precision PCR setup supporting almost all tube and plate formats, as well as Rotor-Discs for the Rotor-Gene Q.
- **ESEQuant** portable, battery-operated instruments enable optical measurement for Point of Need molecular testing in physician practices, emergency rooms, remote areas, and other settings with limited or delayed access to laboratories.

Customers

With a growing portfolio of innovative products for molecular testing, QIAGEN has built deep customer relationships across the entire value chain of the life sciences. Discoveries often surface in universities and research institutes and are published, then are licensed 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 hospitals, public health organizations, reference laboratories and physician practices
- **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 is rapidly disseminating, further transforming healthcare. Technologies for molecular diagnostics enable clinicians and labs to identify and profile microorganisms, cancer cells, bacteria and viruses by detecting specific nucleic acid sequences or characterizing 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 approximately $7 billion in 2017, including about $3-4 billion potentially addressable with QIAGEN's product portfolio. Molecular diagnostics is the most dynamic segment of the global in vitro diagnostics market and is growing at a compound annual 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.

In QIAGEN's robustly growing Molecular Diagnostics business we focus on three priorities for fighting disease:

- **Oncology** - accurately diagnosing cancer, enabling prevention or early detection, and guiding selection of therapies with individualized molecular insights. QIAGEN offers a broad portfolio of companion diagnostic kits

and panels to detect mutations of genes such as KRAS, EGFR, BRAF, BRCA1/2 and others that influence the efficacy and safety of medicines. We also provide industry-leading tests to screen for human papillomavirus (HPV) and protect women from cervical cancer.

- **Infectious diseases** - detecting and differentiating a broad range of viral and bacterial infections, including diseases such as HIV, hepatitis, influenza and healthcare-associated infections. Use of molecular testing to differentiate among pathogens can be useful in guiding treatment, such as selection of antibiotic or antiviral therapies.
- **Immune monitoring** - using advanced technologies that detect immune-system markers as a preventive strategy, such as screening patients for latent TB infection to guard against active TB disease, as well as for monitoring immune function, such as in transplantation patients.

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 process these samples reliably and efficiently, often handling hundreds of samples concurrently. Other success factors are the range of assays for diseases and biomarkers, convenience and ease of laboratory workflow, and reliability and standardization of lab procedures.

The immune monitoring portfolio, using sensitive QuantiFERON technology, accurately detects infection and measures immune response in patients. Our lead products in this field, QuantiFERON-TB Gold and QuantiFERON-TB Gold Plus, are used in tuberculosis (TB) control efforts worldwide to detect latent TB infection (LTBI) by screening vulnerable populations, such as close contacts of patients with active TB disease, immunocompromised persons or patients on immunosuppressive drugs. Individuals with LTBI can then be treated, preventing the infection from becoming active and contagious. As modern blood tests analyzed in a laboratory, the QuantiFERON-TB assays are faster, less labor-intensive and more accurate than the century-old tuberculin skin test. The potential global market for latent TB infection testing is estimated at up to $1 billion.

QIAGEN's oncology test portfolio includes a broad range of Personalized Healthcare technologies and biomarkers, including regulator-approved companion diagnostics for oncogenes such as KRAS, EGFR and JAK2, as well as comprehensive gene panels for research applications in next-generation sequencing. In 2017, we launched the ipsogen JAK2 RGQ PCR Kit in the United States for use in blood cancers. In Europe, we already offer a market-leading portfolio of ipsogen assays for common and rare leukemia types. The U.S. approval for our therascreen EGFR RGQ PCR Kit was expanded in early 2018 for use as a companion diagnostic to diagnose additional EGFR gene mutations in metastatic non-small cell lung cancer (NSCLC).

QIAGEN also offers 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.

QIAGEN 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 careHPV Test for use in low-resource regions lead the market in HPV screening around the world. In the United States, QIAGEN remains a market leader although vigorous price competition has reduced that business to about 2% of total sales.

A key success factor for our growth in Molecular Diagnostics is enabling laboratories to efficiently use our assay technologies on QIAGEN automation platforms. Our flagship PCR platform is QIAsymphony, based on its flexibility and unique capabilities. We offer broad portfolios of companion diagnostics and infectious disease tests running on the QIAsymphony system. We also are developing companion diagnostics for our GeneReader NGS System and Modaplex platform. 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 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 expanding in more areas of life as industry and government organizations apply standardized Sample to Insight 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 environmental 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.

QIAGEN has developed relationships with diverse molecular testing laboratories and continually innovates to meet their needs. In 2017, QIAGEN helped the International Commission on Missing Persons launch a cutting-edge next-generation sequencing lab for forensic DNA identification, deploying the GeneReader NGS System and other solutions. We are a leader in standardizing solutions for reliable forensic testing, and in 2017 we received international certification for manufacturing human ID products. In environmental research, QIAGEN's solutions for metagenomics are increasingly used in studies of microbiomes and their effect on health.

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 also are widely used to guide pharmaceutical research.

We have built a position as the preferred partner for pharmaceutical and biotech companies to co-develop companion diagnostics paired with targeted drugs. A wave of newly discovered biomarkers and molecular tests indicating the likely efficacy and safety of associated drugs is now transforming the treatment of cancer and other diseases. In 2017, we surpassed 25 master collaboration agreements with Pharma, each enabling multiple co-development projects. These alliances have created a rich pipeline of molecular tests that can move, along with the drugs, through clinical trials and regulatory approvals for marketing to healthcare providers. Several new companion diagnostics are currently in the registration process.

In addition to our broad portfolio of molecular technologies, QIAGEN offers Pharma partners 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 or create their own in-house technologies, QIAGEN has focused on enabling labs to replace time-consuming traditional methods and internal development efforts with reliable, fast, highly reproducible, and high-quality technologies. QIAGEN often partners with leading institutions in research projects and develops customized solutions such as NGS panels for digital sequencing of multiple gene targets needed for a researcher's study.

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, Pharma and Applied Testing customer classes. Research in university settings often helps in development of

technologies for targeted biomolecules, and academic research also can result in scientific publications that validate the usefulness of QIAGEN solutions.

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)	2017	2016	2015
Net Sales			
Consumables and related revenues	$ 1,242,715	$ 1,166,131	$ 1,114,580
Instrumentation	174,821	171,860	166,406
Total	$ 1,417,536	$ 1,337,991	$ 1,280,986

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)	2017	2016	2015
Net Sales			
Americas:			
United States	$ 579,906	$ 555,676	$ 525,532
Other Americas	73,478	71,797	79,578
Total Americas	653,384	627,473	605,110
Europe, Middle East and Africa	462,980	428,055	409,955
Asia Pacific and Rest of World	301,172	282,463	265,921
Total	$ 1,417,536	$ 1,337,991	$ 1,280,986

QIAGEN has built an increasing presence in key emerging markets as a growth strategy. In 2017, the top seven emerging markets - Brazil, Russia, India, China, South Korea, Mexico and Turkey - contributed approximately 16% of net sales.

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 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.

As a percentage of sales, our research and development investments are among the highest in our industry. Almost 1,000 employees in research and development work in QIAGEN centers of excellence on three continents.

Strengthening our leadership in the automation of laboratories is a key to driving dissemination of molecular testing in healthcare and other fields, as well as generating increased demand for our consumable products. We continue to expand the applications of our modular QIAsymphony platform, enabling hospitals and other customers to adopt or greatly expand their use of molecular diagnostics. QIAGEN also is rolling out a range of performance enhancements and expansions for our GeneReader NGS System to add value by addressing new applications and improving output and connectivity within labs.

We are commercializing a deep pipeline of assays for preventive screening and diagnostic profiling of diseases, detection of biomarkers to guide personalized medicine in cancer and other diseases, and a range of other targets. Our development program generates commercial launches of tests that add value to our QIAsymphony and GeneReader NGS platforms. In 2017, we launched novel infectious disease tests and companion diagnostics for QIAsymphony, as well as additional QIAact panels for deep analysis of lung, breast and ovarian cancers using the GeneReader NGS System. In Applied Testing, we continue to develop new content for human identification and environmental applications. 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 content 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 differentiated, high-quality products across the value chain from Sample to Insight, integrating components into end-to-end solutions when possible, and enhancing relationships with commitment to technical excellence and customer service. Our "omni-channel" approach seeks to engage customers through their preferred channels - online, by phone, in person, etc. – and to optimize investment in different customer types.

QIAGEN has initiated actions to drive the growth of our digital marketing channels - including our website (www.qiagen.com), product-specific sites and social media. Our website makes ordering easy with a fully

searchable online product catalog and ordering. The site can be viewed in Chinese and Japanese, and contains selected information in French, German and Korean. Our eCommerce team works with clients to provide automated processes supporting a variety of electronic transactions and all major eProcurement systems. 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 approximately 25 million pre-designed and custom PCR assay kits, NGS assay panels and other products. We have integrated GeneGlobe with our bioinformatics solutions, linking biological interpretation with ordering of relevant assays to accelerate research.

QIAGEN uses a range of tools to provide customers with direct access to technical support, inform them of new product offerings, and enhance our reputation for technical excellence, high-quality products and commitment to service. For example, our technical service hotline allows existing or potential customers to discuss a wide range of questions about our products and molecular biology procedures, online or via phone, with Ph.D. and M.Sc. scientists at QIAGEN. Frequent communication with customers enables us to identify market needs, learn of new developments and opportunities, and respond with new products.

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 and at major scientific and clinical meetings. 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 on-site to keep up with their requirements. QIAGEN representatives make regular visits to replenish the stock and help with other needs, and we are automating this process with digital technologies. 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 2017, our purchases of intangible assets totaled $34.3 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, 2017, we owned 362 issued patents in the United States, 279 issued patents in Germany and 1,825 issued patents in other major industrialized countries. We had 638 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 section "Opportunities and Risks" 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 Merck KGaA (MilliporeSigma business) 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 Merck KGaA (MilliporeSigma business) 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.

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 assays include Roche Diagnostics, Thermo Fisher, Abbott, and Danaher. 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 supplier assessment procedures, we evaluate on a monthly basis 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, electronics 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 May 25, 2017, the European Commission (EC) enacted new EU regulations for medical devices and IVDs that impose additional legal regulatory requirements on MD/IVDs used in the EU. These new regulations will come into full effect after a 5-year transition period. All products will require approval under the new law and no grandfathering of existing approvals will be allowed. Once implemented, the entire EU IVD industry will have to comply with these new requirements, which will bring the EU regulatory landscape on par with other highly regulated markets such as the US. Many Guidance Documents and other regulatory mechanisms will need to be

established during this transition. It is anticipated that it will be late in 2019 before the infrastructure is established to begin the new approvals process.

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 PMAs, 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 and some Lab Developed Tests (LDTs). 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, that is subject to frequent adjustment, 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 continues to reevaluate 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

If a sponsor or the FDA believes that a diagnostic test is essential for the safe and effective use of a corresponding therapeutic product, the sponsor of the therapeutic product will typically work with a collaborator to develop an in vitro companion diagnostic device, or IVD. IVDs are regulated by the FDA as medical devices. The FDA issued a final guidance document in 2014, entitled "In Vitro Companion Diagnostic Devices" that is intended to assist companies developing in vitro companion diagnostic devices and companies developing therapeutic products that depend on the use of a specific in vitro companion diagnostic for the safe and effective use of the product. The FDA defined an IVD companion diagnostic device as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. 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 and that, in most cases, the therapeutic product and its corresponding IVD companion diagnostic will be developed contemporaneously.

It also issued a draft guidance on July 15, 2016, entitled, "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product" to serve as a practical guide to assist therapeutic product sponsors and IVD sponsors in developing a therapeutic product and an accompanying IVD companion diagnostic.

The FDA indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion diagnostic devices, as it does with all medical devices. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the IVD companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness. The two primary types of marketing pathways for medical devices are clearance of a premarket notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or 510(k), and approval of a premarket approval application, or PMA. We expect that any IVD companion diagnostic device developed for use with our drug candidates will utilize the PMA pathway and that a clinical trial performed under an investigational device exemption, or IDE, will have to be completed before the PMA may be submitted.

The FDA expects that the therapeutic sponsor will address the need for an IVD companion diagnostic device in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding IVD companion diagnostic device will be developed contemporaneously. If the companion diagnostic test will be used to

make critical treatment decisions such as patient selection, treatment assignment, or treatment arm, it will likely be considered a significant risk device for which a clinical trial will be required.

The sponsor of the IVD companion diagnostic device will be required to comply with the FDA's IDE requirements that apply to clinical trials of significant risk devices. If the diagnostic test and the therapeutic drug are studied together to support their respective approvals, the clinical trial must meet both the IDE and IND requirements.

PMAs must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete.

If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval order or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will send the applicant a not approvable letter or an order denying approval. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

After approval, the use of an IVD companion diagnostic device with a therapeutic product will be stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product. In addition, a diagnostic test that was approved through the PMA process or one that was cleared through the 510(k) process and placed on the market will be subject to many of the same regulatory requirements that apply to approved drugs. 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 as of September 24, 2016 and 2018, respectively. QIAGEN was fully compliant with the new rule by the September 2014 and 2016 deadlines 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, it is possible that some of our RUOs may be used by some customers without our knowledge in their 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.

The 21st Century Cures Act (Cures Act) was enacted into law on December 13, 2016, after a bipartisan, multi-year effort. The Cures Act primarily affects activities of the Department of Health and Human Services (HHS) and its agencies, including the Food and Drug Administration (FDA or the Agency). On June 6, 2017, Scott Gottlieb, M.D., Commissioner of Food and Drugs, reported to Congress as required by the Cures Act. This report included the Food & Drug Administration Work Plan and Proposed Funding Allocations of FDA Innovation Account (Required by Section 1002 of the 21st Century Cures Act (Public Law 114-255). This is now being implemented with a broad spectrum of initiatives within the FDA with the goal to support patients with improved and timely access to safe and efficacious medical products. For industry, it is anticipated that some processes will become less burdensome with more rapid approval/clearance cycles while others will continue to require significant investment.

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 in accordance with HIPAA standards, such as 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. In the ordinary course, HIPAA does not apply to us directly, but if we were to act as a HIPAA covered entity or business associate, we would be subject to these obligations. 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.

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.

The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a federal law that protects individuals from discrimination in the health insurance and employment contexts because of DNA characteristics that may affect their health. GINA prohibits covered employers from requesting, obtaining, or using employees' genetic information (subject to limited exceptions), and prohibits covered health insurers from requesting genetic information or using any such information they may already have for purposes of making eligibility, premium, or coverage-related decisions.

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.

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, such as the General Data Protection Regulation (GDPR) of the European Union, that impose restrictions on the transfer, access, use, and disclosure of health and other personal information. Currently, we are implementing the requirements set forth by the GDPR, which is set to take effect on May 25, 2018. 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 insulate healthcare providers, medical device manufacturers, and others, from prosecution 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.

We have and may in the future, enter into various agreements with health care providers who perform services for us, including some who make clinical decisions to use our products. All such arrangements have been structured with the intention of complying with all applicable fraud and abuse laws, including the Anti-Kickback Statute.

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 federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain “designated health services” if the physician or an immediate family member of the physician has any financial relationship with the entity. Penalties for violating the Stark Law include fines, civil monetary penalties and possible exclusion from federal healthcare programs. In addition to the Stark Law, many states have their own self-referral laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions or safe harbors.

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 manufacturers, including 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, requires manufacturers, including 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.

Despite extensive procedures to ensure compliance, we may also be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibits companies and their intermediaries from making corrupt payments to foreign officials for the purpose of obtaining or maintaining business or otherwise obtaining favorable treatment, and requires companies to maintain adequate record-keeping and internal accounting practices to accurately reflect the transactions of the company. We are also subject to a number of other laws and regulations relating to money laundering, international money transfers and electronic fund transfers. These laws apply to companies, individual directors, officers, employees and agents.

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.

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. This is being led by the International Medical Device Regulators Forum (IMDRF). This Forum consists of regulators from around the world that have signed governmental agreements to align global regulations, especially around submissions and approvals. In the long term this holds the promise of reducing volatility and complexity in the regulatory landscape.

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.

We frequently identify value propositions on our products and communicate them to payors, providers, and patient stakeholders and attempt to positively impact coverage, coding and payment pathways. However, we have no direct control over payor decisions with respect to coverage and payment levels for our products. The manner and level of reimbursement may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) and/or drug(s) utilized, the available budget, or a combination of these factors, and coverage and payment levels are determined at each payor's discretion. Changes in reimbursement levels or methods may positively or negatively affect sales of our products in any given country for any given product. At QIAGEN, we work with several specialized reimbursement consulting companies and maintain regular contact with payers.

As government programs seek to expand healthcare coverage for their citizens, they have at the same time sought to control costs by limiting the amount of reimbursement they will pay for particular procedures, products or services. Many third-party payors have developed payment and delivery mechanisms to support cost control efforts and to focus on paying for quality. Such mechanisms include payment reductions, pay for performance metrics, quality-based performance payments, restrictive coverage policies, studies to compare effectiveness and patient outcomes, and technology assessments. These changes have increased emphasis on the delivery of more cost-effective and quality-driven healthcare 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. CMS uses its own HCPCS codes for medical billing and reimbursement purposes. Level I HCPCS codes reflect current CPT codes, while Level II codes primarily represent non-physician services and Level III codes are local codes developed by Medicaid agencies, Medicare contractors and private insurers.

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.

CMS reimbursement rates for clinical diagnostic tests are defined by HCPS code in the Clinical Laboratory Fee Schedule (CLFS). 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. CMS issued final national reimbursement prices for the new CPT codes in November 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. As of January 1, 2018, in accordance with the Protecting Access to Medicare Act of 2014 (PAMA), CMS began calculating Medicare reimbursement rates for certain clinical diagnostic tests using weighted median private payor rates, which are based on rate information reported by applicable laboratories. This new rate methodology means the lower reimbursement rates previously experienced in the field of molecular pathology testing now extends to additional diagnostic testing codes on the CLFS.

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 an illness or injury. However, most third-party payors do not cover experimental services. Coverage determinations are often influenced by current standards of practice and clinical data, particularly at the local level. CMS, 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 settings is based on the CLF, 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 most recent Conflict Minerals findings to the Securities Exchange Commission for the calendar year ending December 31, 2016 on Form SD on April 24, 2017 and will provide updated disclosure to the Securities Exchange Commission as required.

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 of the 2017 Annual Report on Form 20-F files with the U.S. Securities and Exchange Commission.

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, Germany, Poland and Romania. 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 $90.1 million, $74.5 million and $97.8 million for 2017, 2016 and 2015, 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 13485:2012, 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 781,000 square feet, some of which is leased pursuant to separate contracts, the last of which expires in 2018. Our most recent expansion to these facilities was in 2017 and included approximately 4,400 square feet of additional office and warehouse space. Our production capacity is increased through our manufacturing and research facilities in the United States. QIAGEN Sciences, LLC owns a 24-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 42,000 square feet for manufacturing, warehousing, distribution and research operations. We also lease facilities in Massachusetts with 32,400 square feet in Waltham for NGS system development and 39,100 square feet in Beverly for enzyme manufacturing. Additionally, we have

leased facilities in Redwood City, California with 12,700 square feet and Cary, North Carolina with 10,900 square feet focused on bioinformatics. Additionally, we lease smaller facilities in Shenzhen, China and Manchester, United Kingdom for manufacturing, warehousing, distribution and research operations and have shared service centers which lease facilities in Wroclaw, Poland and Manila, Philippines. 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.