Management Report

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 customers across the continuum of molecular testing to unlock valuable insights faster, better and more efficiently - from the raw biological sample to the final interpreted result.

We serve more than 500,000 customers in two broad customer groups: Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). Proven QIAGEN solutions and content are providing answers in hospitals and laboratories worldwide, helping make sense of the increasing volumes and complexity of biological information, in keeping with our vision of making improvements in life possible.

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 and genomic knowledge have 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 Digital Insights solutions allow users to analyze and interpret data with bioinformatics software and knowledge bases to provide relevant, actionable insights. Our automation systems tie these technologies together in seamless and cost-effective molecular testing workflows - from Sample to Insight.

Net sales of $1.53 billion in 2019 consisted of consumable kits and other revenues (89% of sales) and automation systems and instruments (11% of sales). Approximately 48% of net sales in 2019 were in Molecular Diagnostics, and 52% in Life Sciences customer classes in the Academia / Applied Testing and Pharma markets.

QIAGEN has grown by developing new instruments, consumables and digital solutions to meet diverse and 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 $10 billion.

We have funded our growth through internally generated funds, debt offerings, and private and public sales of equity securities. QIAGEN's global shares 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.

On March 3, 2020, QIAGEN and Thermo Fisher Scientific Inc. (NYSE: TMO) announced that their boards of directors, as well as the managing board of QIAGEN N.V., unanimously approved Thermo Fisher's proposal to acquire QIAGEN for €39 per share in cash. The offer price represents a premium of approximately 23% to the closing price of QIAGEN's common stock on the Frankfurt Prime Standard on March 2, 2020, the last trading day prior to the announcement of the transaction. Thermo Fisher will commence a tender offer to acquire all of the ordinary shares of QIAGEN. The transaction values QIAGEN at approximately $11.5 billion at current exchange rates, which includes the assumption of approximately $1.4 billion of net debt. The transaction, which is expected to be completed in the first half of 2021, is subject to the satisfaction of customary closing conditions, including the receipt of applicable regulatory approvals, the adoption of certain resolutions relating to the transaction at an Extraordinary General Meeting of QIAGEN's shareholders, and completion of the tender offer.

Operating Environment in 2019

Economic Environment

Global economic growth decelerated in 2019 amid weakness in global trade and investment, providing a challenging business environment for QIAGEN operations. Real Gross Domestic Product (GDP) for the world grew an estimated 2.4% in 2019, decelerating from 3.0% in 2018 and 3.2% in 2017, the World Bank reported. Advanced economies including the United States, the Euro area and Japan delivered slower growth in 2019. Emerging markets as a whole also decelerated, with slower growth in China, India and many developing countries. Growth in global trade slowed in 2019 amid challenges including tariffs, geopolitical developments and weaker demand in Europe and Asia, although trade tensions eased somewhat late in the year. Central banks including the U.S. Federal Reserve and the European Central Bank reduced interest rates and took other actions in 2019 to ease monetary policy and counter the slowdown in economic growth. The U.S. dollar strengthened against other currencies in 2018, with a negative impact of about 2 percentage points on growth in QIAGEN sales reported in dollars.

Industry Environment

As genomic knowledge expands exponentially, molecular testing continues to grow to meet needs for insights in diagnostics, life science research, pharmaceutical R&D and public safety. Technologies for next-generation sequencing (NGS) and polymerase chain reaction (PCR) continued to disseminate and evolve in 2019, making molecular testing more accessible, faster and more efficient. Molecular diagnostics kept growing dynamically and expanding into new areas of medicine – enabling clinicians to evaluate and monitor cancers, infectious diseases, immune status, and prenatal or neonatal health. In 2019, 11 of the 44 new drugs approved by the FDA were targeted with biomarker testing; in addition, 15 existing drugs gained new indications targeted with biomarker testing. Reimbursement for precision medicine, however, remained a challenge. In Academia, spending on NGS and other molecular technologies continued to grow despite perennial uncertainties about research funding. Pharma industry spending on R&D also grew in 2019, with DNA and RNA tests providing critical insights for drug discovery and clinical trials. The migration of genomic technologies from basic research into the mainstream remains 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 milestones by continuing to focus on strategic growth initiatives:

Sustaining the rapid growth of our QuantiFERON-TB franchise:

- QIAGEN's QuantiFERON-TB tests play an increasingly central role in the global fight against tuberculosis (TB), a contagious bacterial infection that strikes more than 10 million new patients and kills about 1.7 million annually. Guidelines from the World Health Organization (WHO) and leading clinical organizations now recommend screening of high-risk individuals for latent TB infection and preventive treatment as a component of TB control programs.
- Sales of the QuantiFERON-TB franchise, including the fourth-generation QuantiFERON-TB Gold Plus (QFT-Plus), grew 8% in 2019 to $240 million.
- In November 2019 QIAGEN and DiaSorin announced the U.S. launch of the LIAISON QuantiFERON-TB Gold Plus test as a streamlined, highly automated option for latent TB screening programs from small-scale to high-throughput. QIAGEN and DiaSorin introduced QFT-Plus on LIAISON analyzers in Europe in late 2018, added the U.S. market following the recent FDA approval, and are planning availability for China in 2020.
- In October 2019 the Stop TB Partnership's Global Drug Facility (GDF) added QFT-Plus to its diagnostic catalog, opening a new channel to reach countries with a high incidence of TB but limited resources. The GDF helps match global demand with funding from donors, governments and non-governmental organizations.
- QIAGEN continues to innovate in latent tuberculosis testing. In partnership with Ellume, QIAGEN is developing QuantiFERON-TB Access, a simplified, low-cost test offering ultrasensitive digital detection in a workflow designed for cost-efficiency and use in areas lacking laboratory infrastructure. The product will further advance global TB control efforts, particularly in low-resource and high-burden regions. Commercialization is expected to begin in 2020.

Driving growth in next-generation sequencing (NGS) with greater focus:

- QIAGEN continues to expand our global presence in the fast-growing market for next-generation sequencing (NGS). In 2019 we shifted our strategy and reoriented our NGS activities to focus on opportunities to build upon our strengths as a leader in "universal" technologies for preparing samples, analyzing genomic variations and interpreting sequencing data.
- NGS-related sales in 2019 achieved QIAGEN's goal of more than $180 million, compared to over $140 million in 2018. Demand for our universal NGS technologies and Digital Insights from bioinformatics applications drove this growth.
- In October 2019 QIAGEN and Illumina, Inc. announced a 15-year partnership to broaden the use of NGS-based in vitro diagnostic kits to deliver insights for clinical decision-making, including companion diagnostics for precision medicine. Illumina and QIAGEN will cooperate to commercialize a menu of clinically validated workflows that combine QIAGEN's proprietary content and digital solutions for use with Illumina's MiSeq Dx, NextSeq 550Dx and future diagnostic systems. In the coming years we expect the partnership with Illumina, whose sequencing instruments are in widespread use worldwide, to expand our global presence in clinical decision-making using NGS technology.
- QIAGEN also announced in October 2019 that we have discontinued development of new NGS instruments. We will focus NGS-related development resources on maximizing the new Illumina partnership for NGS-based diagnostic kits, as well as expanding our offering of universal NGS consumables for use with any sequencer. QIAGEN intends to continue supporting and servicing customers of the GeneReader NGS System, which is available as a complete system for the processing of smaller targeted gene panels, but we do not expect to develop new sequencing platforms at this time.

- We continue to expand QIAGEN's broad portfolio of universal, or platform-agnostic, NGS solutions. Among the new products introduced in 2019 are QIAseq Multimodal Panels, the industry's only consolidated workflow to simultaneously detect DNA variants, RNA fusions and gene expression levels from a single sample; QIAseq FastSelect kits to remove unwanted RNA from samples, addressing critical bottlenecks in research into RNA and gene expression; and the QIAseq Expanded Carrier Screening Panel, enabling identification of genetic drivers of more than 200 rare and inherited diseases.

Reaping the value of genomic insights for Precision Medicine:

- QIAGEN continues to lead our industry in precision medicine, collaborating with more than 25 pharmaceutical and biotech companies to develop companion and complementary diagnostics to guide clinical decision-making. These partnerships feed a deep pipeline of Sample to Insight tests supporting clinical trials and, with regulatory approvals, patient care.
- In 2019 three of our co-development partnerships bore fruit in newly approved companion diagnostics in oncology. We introduced the therascreen PIK3CA RGQ PCR Kit in the U.S. as a companion diagnostic to aid in identifying patients for a new breast cancer therapy developed by Novartis (launched in Europe in early 2020); the therascreen FGFR RGQ RT-PCR Kit to help identify U.S. urothelial cancer patients for Janssen Biotech's newly approved FGFR kinase inhibitor; and the therascreen EGFR RGQ PCR Kit in Japan - our first companion diagnostic approval there - to help guide the use of a new Pfizer therapy in non-small cell lung cancer (NSCLC). All three run on the Rotor-Gene Q, a module in our QIAsymphony system.
- A partnership with Inovio Pharmaceuticals, launched in May 2019, will co-develop a liquid-biopsy companion diagnostic for Inovio's DNA-based immunotherapy compound, which has potential to be the first treatment for human papillomavirus (HPV) infection of the cervix and first non-surgical treatment for precancerous lesions associated with the virus.
- A new collaboration with Amgen announced in early 2020 will develop tissue-based companion diagnostics to identify non-small cell lung cancer patients who would benefit from Amgen's investigational cancer treatment AMG 510. The test will identify patients with cancers that have the KRAS G12C genetic mutation, a common cause of cancer.
- We expanded our Day-One Lab Readiness network in 2019 through collaborations with CLIA-certified laboratories to ensure immediate patient access to QIAGEN companion diagnostics upon approval of new oncology drugs. Among the clinical labs now participating to accelerate patient access are LabCorp, Quest, NeoGenomics, SRL in Japan, and others.

Expanding QIAGEN automation solutions to serve growing market needs:

- QIAGEN has strategically expanded our offering of automation solutions to enter growing segments of the life science and molecular diagnostics markets, as well as to meet the diverse, rapidly evolving needs of customers.
- The QIAsymphony system, a cost-effective modular automation solution that integrates PCR molecular testing from sample processing to final insights, surpassed our goal of 2,500 cumulative placements by year-end 2019. Related consumables grew globally, including an extensive menu of in vitro diagnostic tests in infectious disease, oncology and transplant care. The sample processing module, QIAsymphony SP, is a market-leading "front end" solution for reliable automated handling of samples, including liquid biopsies, for PCR and next-generation sequencing.

- The QIAstat-Dx system is approaching 1,000 cumulative placements, providing fast, cost-effective and easy-to-use syndromic testing with novel Sample to Insight solutions. In May 2019, we launched the platform in the United States with an FDA-cleared multiplex panel for differential diagnosis of respiratory infections. QIAstat-Dx was introduced in Europe in 2018 with CE-IVD marked panels for respiratory and gastrointestinal infections. The system produced $15 million of sales in 2019. In early 2020, QIAGEN created a version of the QIAstat-Dx respiratory panel for potential use in testing of patients for COVID-19 in China and other markets using the QIAstat-Dx platform. Additional diagnostic panels are planned to launch in 2020 to enhance the value to clinics and physician offices.
- The NeuMoDx 96 and 288 Molecular Systems are providing fully integrated, mid- to high-throughput PCR analysis systems for clinical laboratories, and now have eight CE-IVD cleared diagnostic kits covering a range of infectious diseases. QIAGEN has the right to commercialize these platforms in Europe and other markets outside the U.S.
- Our development of disruptive new systems for digital PCR is on track to begin commercialization in 2020, combining proprietary QIAGEN technologies with assets acquired from Formulatrix in early 2019. Our digital PCR initiative aims to provide fully-integrated solutions that simplify workflows for laboratories, offer higher throughput and multiplexing, and provide customers with favorable costs for instruments and consumables.

Digital Insights solutions transforming raw data into valuable insights:

- As genomic data increasingly influences decisions in science and healthcare, QIAGEN's Digital Insights solutions are driving growth with content-enabled bioinformatics that transform raw NGS data into actionable insights for customers.
- Researchers worldwide use our software and industry-leading knowledge bases to accelerate innovation, guide experiments and translate genomic results into actions that enhance clinical care. Starting in 2014, QIAGEN has built a comprehensive, easy-to-use toolbox through acquisitions of Ingenuity, CLC bio, BIOBASE and OmicSoft. Digital Insights solutions are marketed as standalone products and integrated into QIAGEN Sample to Insight workflows to meet customer needs.
- In June 2019, our industry-leading QIAGEN Clinical Insight (QCI), a clinical decision support platform for interpretation and reporting of next-generation sequencing data, achieved a milestone of more than 1 million patient test cases analyzed and interpreted. We continually update and expand the content available through QCI. After acquiring N-of-One, Inc. in January 2019, we integrated N-of-One's services and somatic cancer database, including medical interpretation and real-world evidence from more than 125,000 anonymized patient samples, into QIAGEN Clinical Insight.

Pioneering differentiated sample technologies and liquid biopsy solutions:

- As a leader in sample technologies enabling laboratories to obtain highest-quality DNA and RNA for molecular testing, QIAGEN continues to innovate with front-end solutions in growing fields. QIAGEN technologies process an estimated 50,000 biological samples a day. In 2019 we rolled out several new products solving tough challenges for customers, such as new tools to accelerate RNA sequencing for research and liquid biopsies for efficient, less-invasive diagnosis.
- Our QIAcube Connect system, launched in January 2019 to amplify the benefits of automated sample processing for customers, reached more than 660 placements by year-end, with strong Life Sciences demand. Building on over 8,000 placements of our first-generation QIAcube instrument, QIAcube Connect delivers a new level of digitization and ease of use with thousands of protocols, assuring full standardization and freeing customers from repetitive manual processing.

- QIAGEN offers an innovative portfolio of liquid biopsy technologies for research and clinical applications. Liquid biopsies extract and purify DNA and RNA from blood or other body fluids, as an alternative to costly and sometimes impractical tissue biopsies. In 2019, our therascreen PIK3CA RGQ PCR Kit became the first FDA-approved liquid biopsy test using blood plasma to guide treatment decisions in breast cancer.
- In October 2019, we launched innovative new QIAseq FastSelect kits for customers in Life Sciences to remove unwanted RNA from biological samples for faster, simpler library preparation. The solutions address critical bottlenecks in RNA sequencing, enabling scientists to achieve more on-target NGS reads and more efficient use of resources.

Executing initiatives to prioritize resource allocation and create value:

- QIAGEN implemented several organizational changes and portfolio initiatives in 2019 with the aim of driving future growth, efficiency and profitability. These actions prioritized resource allocation to streamline operations, strengthen the focus on execution and improve operating margins.
- In October 2019, QIAGEN stopped internal development of new instruments for next-generation sequencing, restructuring to allocate resources from work on new proprietary NGS systems to QIAGEN's partnership with Illumina to commercialize in vitro diagnostic kits running on Illumina's clinical NGS platforms, as well as to universal NGS portfolio.
- Streamlining initiatives in 2019 aimed to create a more focused, agile and efficient global operation. Changes included shifting worldwide production into a regional structure, integrating global sales resources into the three Business Areas (Life Sciences, Molecular Diagnostics and QIAGEN Digital Insights), and moving additional activities to QIAGEN Business Services centers in Poland and the Philippines.
- Digitization of a wide range of customer interactions continues to progress, with approximately 43% of 2019 sales coming via the QIAGEN website and other online channels.

Products

QIAGEN's leadership in Sample to Insight solutions for molecular testing leverages our product portfolio across a wide range of applications and customer classes. We provide more than 500 core consumable products (sample and assay kits), instruments and automation systems, and digital insight solutions (or bioinformatics) for analysis and interpretation.

These diverse revenue streams comprise two main categories: **Consumables and related revenues**, approximately 89% of net sales in 2019, including sample and assay kits, digital insights, royalties, co-development milestone payments and services; and **Automation platforms and instruments**, approximately 11% of net sales in 2019, including related services and contracts.

QIAGEN automation systems streamline molecular testing using consumables in efficient workflows and carrying customers through the process from Sample to Insight. Some QIAGEN consumables are designed to run on QIAGEN instruments, while others are universal kits designed for use with any molecular testing platform.

Major types of QIAGEN solutions and related brands

Sample Technologies

Our broad portfolio of sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other biological materials to prepare for a wide variety of molecular testing needs in research and clinical applications.

Sample Technologies	Selected QIAGEN brands		
Primary sample technology consumables			
• Nucleic stabilization and purification kits designed for primary sample materials (DNA, RNA, proteins), manual and automated processing for genotyping, gene expression, viral and bacterial analysis	• QIAamp	• DNeasy	• RNeasy
	• PAXgene	• AdnaTest	• Tiangen
• Mainly based on silica membranes and buffers	• Gentra Puregene	• Oligotex	• AllPrep
		• BioSprint	
Secondary sample technology consumables			
• Kits and components for purification of nucleic acids and proteins from secondary sample materials (e.g. gel, plasmid DNA, proteins)	• QIAprep	• QIAquick	• DyeEx
	• Qproteome	• BioMag	• Ni-NTA
• Molecular biology reagents	• QIAGEN Plasmid Plus	• QIAfilter	• R.E.A.L.
	• HiSpeed	• EndoFree	
Sample technology instruments			
• Instruments for nucleic acid purification and accessories	• QIAsymphony SP	• QIAcube Connect	• QIAcube HT
	• QIAscout	• Centrifuges	• TissueLyser

Assay Technologies

Targeted or multiplex assay technologies deploy a variety of methods to amplify biomolecules and make them visible and ready for molecular analysis using different techniques.

Assay Technologies	Selected QIAGEN brands		
Assay content consumables			
• Kits, assays, reagents and controls for identification and analysis of sequence-specific targets (such as DNA, methylated DNA, bacterial DNA, RNA, miRNA) with different technologies (such as PCR, Pyrosequencing, hybridization) in assay and array format	• EpiTect	• ADNATest	• miCURY
	• GapmeR	• qBiomarker	• RT^2
• Oligonucleotide synthesis, siRNAs, bisulfite conversion	• miScript	• AllStars	• FlexiTube/FlexiPlate
Enzymatics consumables			
• Custom-developed and configured enzymes and products which are sold to OEM customers	• EnzScript	• Phoenix Hot Start	• VeraSeq
	• ZipScript		
Assay foundation consumables			
• Different generations of PCR, qPCR, reverse transcription and combinations (RT-PCR) kits for analysis of gene expression, genotyping and gene regulation, running on QIAGEN or third-party instruments and technologies	• QuantiTect	• QuantiFast	• QuantiNova
	• OneStep RT-PCR	• Rotor-Gene	• HotStarTaq
• Similar product portfolio developed and sold through QIAGEN second brands (Quanta, Tiangen)	• Type-it	• QIAGEN Multiplex	• TopTaq
	• OmniScript	• SuperScript	• HiPerFect
• QIAxpert consumables, cloning kits and transfection reagents	• PolyFect	• SuperFect	
Assay instruments			
• Modular PCR system with Sample to Insight laboratory automation	• QIAsymphony RGQ	• QIAsymphony AS	• Rotor-Gene-Q
• One-step molecular analysis of hard-to-diagnose syndromes	• QIAstat-Dx	• NeuMoDx 96	• NeuMoDx 288
• Fully integrated medium- to high-throughput PCR test analysis	• PyroMark	• QIAxpert	• QIAxcel
• Specialized instruments for assay setup and analysis	• QIAgility		
Custom laboratory and genomic services			
• Custom services such as DNA sequencing, qPCR service, whole genome amplification, and non-cGMP DNA production	• Provided on an individualized contract basis		

Next-Generation Sequencing (NGS)

High-throughput or next-generation sequencing (NGS) enables analysis of multiple sequences in parallel, using massive analytical and computing power to generate date for a profile of a whole genome or portion of a genome.

Next-Generation Sequencing (NGS)	Selected QIAGEN brands		
Universal NGS consumables			
• Predefined and custom NGS gene panels (DNA, RNA), library prep kits and components, whole genome amplification, etc.	• QIAseq	• REPLI-g	• GeneRead
Digital Insights solutions			
• Bioinformatics solutions to deliver actionable insights from NGS data, sold as freestanding software or cloud-based solutions, also integrated into many QIAGEN consumables and instruments	• QIAGEN Clinical Insight	• CLC Genomics Workbench	• OmicSoft
	• N-of-One	• QIAGEN Knowledge Base	• HGMD
	• Ingenuity Variant Analysis	• Ingenuity Pathway Analysis	

Forensics and Human Identification

Genetic analysis used for forensics and human identification can positively identify or rule out identification of individuals or biological substances for purposes such as law enforcement investigation, paternity testing or food safety screening.

Forensics and Human Identification	Selected QIAGEN brands	
Human ID / Forensics sample collection consumables		
• Sample cards and collection swabs	• FTA	• Other consumables
Human ID / Forensics consumables		
• STR assays for Human ID, additional assays for food contamination	• Investigator (human ID / forensics)	• mericon (food safety)

Customers

With a growing portfolio of innovative products for molecular testing, QIAGEN has built customer relationships across the entire value chain of Life Sciences and Molecular Diagnostics. Discoveries often surface in universities and research institutes, 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 organize our business to serve the needs of major customer classes:

› Molecular Diagnostics - healthcare providers engaged in patient care including hospitals, public health organizations, reference laboratories and physician practices

- Life Sciences - researchers in universities, research institutes and industry customers using molecular testing to achieve new insights into disease or other biological processes, as well as applying molecular testing in non-healthcare fields
  - *Academia / Applied Testing* - exploring the secrets of life such as disease mechanisms and pathways, translating findings into drug targets or other products, or serving purposes such as forensics and human identification
  - *Pharma* - pharmaceutical and biotechnology companies engaging in the R&D process from drug discovery to translational medicine and then clinical development

Molecular Diagnostics

QIAGEN offers one of the broadest portfolios of molecular technologies for healthcare, and Molecular Diagnostics customers accounted for $737 million of our sales in 2019. The success of molecular testing in healthcare depends on the ability to accurately analyze purified nucleic acid samples from sources such as blood, tissue, body fluids and stool. Automated systems must process tests reliably and efficiently, often handling hundreds of samples concurrently. The range of assays for diseases and biomarkers, convenience and ease of laboratory workflow, and standardization of lab procedures also influence success.

The molecular diagnostics market generates total sales estimated by industry experts at approximately $7 billion in 2019, including about $5 billion potentially addressable with QIAGEN's product portfolio. Molecular testing is the most dynamic segment of the global in vitro diagnostics market, growing at an estimated annual rate in the mid-single-digits at constant exchange rates. 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 Molecular Diagnostics business we focus on three priorities for fighting disease:

- **Oncology** - accurately diagnosing cancer, enabling prevention or early detection, as well as guiding selection of therapies with individualized molecular insights for precision medicine.

  QIAGEN's oncology test portfolio includes a broad range of technologies and biomarkers for Precision Medicine, including regulator-approved companion diagnostics for oncogenes such as KRAS, EGFR BRCA1/2, JAK2, PIK3CA and others, as well as comprehensive gene panels for research applications in next-generation sequencing. We also provide industry-leading tests to screen for human papillomavirus (HPV) and protect women from cervical cancer.

  We have a deep pipeline of oncology tests for PCR and NGS analysis under development. In addition to our portfolio of molecular technologies and automation systems, QIAGEN offers Pharma partners a full infrastructure for co-development programs, intellectual property on platforms and content, regulatory experience, global marketing reach, and independence as a company focusing exclusively on these types of technologies.

- **Immune monitoring** - using advanced tests to detect immune-system markers as a preventive strategy, such as screening patients for latent tuberculosis infection to guard against active TB disease, or to monitor immune function, for example in transplant patients. Our sensitive QuantiFERON technology accurately detects infection and measures immune response.

Our lead products in this field, QuantiFERON-TB Gold Plus and QuantiFERON-TB Gold, are used in tuberculosis control efforts worldwide to detect latent TB infection (LTBI) by screening vulnerable populations, including 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.

In transplantation, our QuantiFERON Monitor provides monitoring of immune function in solid organ transplant patients and QuantiFERON-CMV Kit tests immunity for infection with cytomegalovirus (CMV) in at-risk patients.

› **Infectious diseases** - detecting and differentiating viral and bacterial infections - such as HIV, hepatitis, influenza, sexually transmitted diseases and healthcare-associated infections, as well as respiratory and gastrointestinal syndromes - can be useful in guiding treatment, such as selection of appropriate antibiotic or antiviral therapies.

QIAGEN offers an extensive range of kits for diagnosing infectious diseases, including a broad menu of reliable tests on the QIAsymphony and NeuMoDx automation systems, as well as QIAstat-Dx panels for respiratory and gastrointestinal syndromes. We are expanding this portfolio by seeking regulatory approvals of new assays across these platforms.

QIAGEN remains a 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, vigorous price competition has reduced QIAGEN's HPV business to about 1% of total sales.

Life Sciences

QIAGEN partners with customers across diverse disciplines in academia and industry, providing sample technologies, assay technologies, Digital Insights and services to universities and institutes, Pharma and biotech companies, government and law enforcement agencies. Life Sciences customers accounted for $789 million of our sales in 2019.

Academia / Applied Testing

QIAGEN provides Sample to Insight solutions to academic and research institutions around the world. We focus on enabling researchers to use reliable, fast, highly reproducible and high-quality technologies, sometimes replacing time-consuming traditional or in-house methods. QIAGEN often partners with leading institutions in research projects and develops customized solutions such as NGS panels for digital sequencing of multiple gene targets. 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 Pharma and Molecular Diagnostics markets.

Applied Testing customers make up the growing market for molecular testing beyond research and human healthcare. QIAGEN is a global leader in solutions for governments and industry, particularly in forensic testing and human identification. The value of genetic "fingerprinting" has been proven in criminal investigations and examinations of paternity or ancestry, as well as food safety and veterinary diagnostics. QIAGEN provides sample collection and analytical solutions for law enforcement and human identification labs, as well as advanced technologies for studies of microbiomes and their effect on health and the environment.

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 to these companies support research, while the other half supports clinical development, including stratification of patient populations based on genetic information. QIAGEN Digital Insights solutions also are widely used to guide pharmaceutical research.

In Precision Medicine, we have built a position as the industry's preferred partner to co-develop companion diagnostics paired with targeted drugs. QIAGEN's more than 25 master collaboration agreements with Pharma customers, some with multiple co-development projects, have created a rich pipeline of molecular tests that are transforming the treatment of cancer and other diseases. Companion diagnostics can move through clinical trials and regulatory approvals, along with the paired drugs, to commercialization and marketing to healthcare providers.

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 related revenues including bioinformatics solutions, and revenues derived from instrumentation sales.

(in thousands)	2019	2018	2017
Net Sales			
Consumables and related revenues	$ 1,354,147	$ 1,315,459	$ 1,242,715
Instrumentation	172,277	186,389	174,821
Total	$ 1,526,424	$ 1,501,848	$ 1,417,536

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)	2019	2018	2017
Net Sales			
Americas:			
United States	$ 663,869	$ 632,660	$ 579,906
Other Americas	58,121	60,359	73,478
Total Americas	721,990	693,019	653,384
Europe, Middle East and Africa	487,476	490,301	462,980
Asia Pacific and Rest of World	316,958	318,528	301,172
Total	$ 1,526,424	$ 1,501,848	$ 1,417,536

QIAGEN has built an increasing presence in key emerging markets as a growth strategy. The top seven emerging markets - Brazil, Russia, India, China, South Korea, Mexico and Turkey - contributed approximately 16% of net sales in 2019, 2018 and 2017.

Research and Development

We are committed to expanding our global leadership in Sample to Insight solutions in Molecular Diagnostics and the Life Sciences. We target our research and development resources to the most promising technologies to address the unmet needs of our customers in healthcare and research labs in key geographic markets.

As a percentage of sales, our research and development investments are among the highest in our industry. About 950 employees in research and development work in QIAGEN centers of excellence on three continents.

Innovation at QIAGEN follows parallel paths:

- Creating new systems for automation of workflows - platforms for laboratories, hospitals and other users of novel molecular technologies.
- Expanding our broad portfolio of novel content - including assays to detect and measure biomarkers for disease or genetic identification.
- Integrating Digital Insights with the testing process - software and cloud-based resources to interpret and transform raw molecular data into useful insights.

Innovation in automation systems positions QIAGEN in fast-growing fields of molecular testing, as well as generating ongoing demand for our consumable products. We are developing and commercializing a deep pipeline of assays for preventive screening and diagnostic profiling of diseases, detection of biomarkers to guide Precision Medicine in cancer and other diseases, and other molecular targets. Our assay development program aims to commercialize tests that will add value to our QIAsymphony, QIAstat-Dx and NeuMoDx automation systems in the coming years, as well as next-generation sequencing kits to support our universal NGS franchise and our in vitro diagnostics partnership with Illumina. In 2019, we launched novel companion diagnostics on the QIAsymphony platform for breast, lung and urothelial cancers. We also added the FDA approved respiratory panel for infectious diseases to the menus for QIAstat-Dx and the NeuMoDx 96 and 288 platforms.

QIAGEN collaborates with many institutions and companies to create innovative molecular solutions. In May 2019, partnering with U.K.-based organizations, we launched APIS Assay Technologies Ltd., a new company aiming to accelerate biomarker commercialization by bridging the translational gap between genomic discoveries and the development of new diagnostics.

Our Digital Insights teams are developing new software and adding proprietary cloud-based content to support the latest research and clinical trends in molecular testing, especially the interpretation of large volumes of NGS data. We also integrate digital solutions 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 in the Americas, Europe, Australia and Asia with the greatest sales potential. Experienced marketing and sales staff, many of them scientists with academic degrees in molecular biology or related areas, sell our products and support our customers. Business managers oversee key accounts 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 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 Design & Analysis Hub (www.geneglobe.com), upgraded in September 2019, 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. The new hub brings next-level experiment planning, execution and follow-up to life science researchers, linking our Digital Insights solutions with ordering of 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 and webinars 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 customers' activities are slowed such as during times of higher unemployment, vacation periods or delays in 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. Additionally, we have customers who are active in the diagnostics testing market, and sales to these customers fluctuate to the extent their activities are impacted by public health concerns such as the timing and severity of flu season.

Intellectual Property, Proprietary Rights and Licenses

We have made and expect to continue to make investments in intellectual property. In 2019, additions to our intangible assets outside of business combinations totaled $286.2 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, 2019, we owned 352 issued patents in the United States, 275 issued patents in Germany and 1,700 issued patents in other major industrialized countries. We had 558 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 “Risks” included in the “Opportunities and Risks” section below 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 in these markets. 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, companies with a focus on nucleic acid separation and purification, assay solutions, transfection reagents and 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. 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 supply performance of our raw material and component suppliers, and we assess on a continuous basis potential alternative sources of such materials and components, and on a yearly basis assess 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. We have inventory agreements with the majority of our suppliers and 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) have been regulated under EU-Directive 98/79/EC (IVD Directive) and corresponding national provisions, however, this Directive will be replaced by the In Vitro Diagnostic Device Regulation (IVDR) in May 2022. 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 13485:2016, 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.

Under the IVDR, which was enacted by the European Commission (EC) on May 25, 2017, in vitro diagnostics will be subject to additional legal regulatory requirements after the IVDR comes into full effect on May 26, 2022. 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 period and it is anticipated that it will be late in 2020 before the infrastructure is established to begin the new approvals process.

U.S. Regulations

In the United States, in vitro diagnostic products are subject to regulation by the FDA as medical devices to the extent that they are intended for use in the diagnosis, treatment, mitigation or prevention of disease or other conditions. They are subject to premarket review and postmarket controls which will differ depending on how the FDA classifies a specific IVD. Certain types of tests like some that we manufacture and sell for research use only in the United States have not been subject to FDA's premarket review and controls because 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. Other tests, known as laboratory developed tests (LDTs) which are in vitro diagnostic tests that are designed, manufactured and used within a single laboratory, have generally been subject to enforcement discretion, which means that FDA generally has not enforced premarket review and other applicable FDA requirements. However, as LDTs have increased in complexity, the FDA has begun to take a risk-based approach to their regulation. 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 Vitro Diagnostics

The FDA regulates the sale or distribution of medical devices, including in vitro diagnostic test kits and some 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 depending on 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 requirements, and adherence to the FDA's quality system regulations (QSRs), which are device-specific current good manufacturing practices. Class II devices are subject to premarket notification, QSRs, general controls and sometimes 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. 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 user fee, that is typically adjusted annually, to the FDA is usually required when a 510(k) notice or premarket approval application is submitted.

510(k) Premarket Notification. A 510(k) premarket 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 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" (NSE) determination 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. A person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a de novo request for the FDA to make a risk-based evaluation for classification of the device into Class I or II. Devices that are classified through the de novo process may be marketed and used as predicates for future 510(k) submissions. The FDA continues to reevaluate the 510(k) pathway and process and the de novo process, and has taken what it describes as a risk-based approach to develop innovative regulatory policy to propose a more "contemporary" approach. In October 2017, the FDA published a final guidance entitled, "De Novo Classification Process (Evaluation of Automatic Class III Designation)" and in December 2018, the FDA issued a proposed rule which if finalized is intended to provide structure, clarity and transparency on the de novo classification process. We cannot predict what if any changes will occur or how they will affect our current or future products.

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 and on December 7, 2018, it published another draft guidance, "Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products" which, if finalized, is intended to facilitate class labeling on diagnostic tests for oncology therapeutic products, where scientifically appropriate.

The FDA also introduced the concept of complementary diagnostics that are distinct from companion diagnostics because they provide additional information about how a drug is used or identify patients who are likely to derive the greatest benefit from therapy without being required for the safe and effective use of that drug. The FDA has not yet provided much guidance on the regulation and use of complementary diagnostics, but several have been approved.

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.

Unique Device Identifier Requirements

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, artus, and therascreen products. We established a task force to ensure that the deadline was met but there is 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 were required to have this same labeling as of September 24, 2016 and 2018, respectively. QIAGEN was fully compliant with the new rule by September 2018. The new rule will also require additional compliance oversight now that it has been implemented. The requirements are now confirmed as part of our annual reporting and PMA submissions. They are also assessed during site inspections by the U.S. FDA.

Regulation of Research Use Only Products

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 (collectively, 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, de-identify information or take some other step so that we may provide services involving PHI. 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.

All 50 states have adopted data breach notification laws relating to the "personal information" of their 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. An increasing number of states are broadly including "health information" as personal information protected under the law. There is significant variability under these laws, but most require notification to affected individuals and 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.

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.

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, the California Consumer Privacy Act of 2018, which took effect on January 1, 2020, imposes requirements and protections upon the processing of personal data, aimed at giving California consumers more visibility and control over their personal information. There are also 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. We have implemented the requirements set forth by the GDPR, which took 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 be 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 anti-inducement law (Section 1128A(a)(5) of the Social Security Act), prohibits providers from offering anything of value to a Medicare or Medicaid beneficiary to induce the beneficiary to use items or services covered by either program. Additionally, the Civil Monetary Penalties Law (Section 1128A of the Social Security Act), authorizes the United States Department of Health and Human Services to impose civil penalties administratively for various fraudulent or abusive acts.

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 care programs such as Medicare or Medicaid; and, in most cases the patients themselves. For many years, federal and state governments in the United States have pursued methods to reduce the cost of healthcare delivery. 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 payors.

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 identifies codes, along with descriptions, 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. Proprietary Laboratory Analyses (PLA) Codes are an addition to the CPT® code set approved by the AMA CPT® Editorial Panel. They are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.

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 or the PLA Code or both. In addition, Z-Code identifiers are unique five-character alphanumeric tracking codes associated with a specific molecular diagnostic test. When a claim is submitted, it includes the associated CPT code and the Z-Code identifier is entered as a device code. 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 CPT and HCPS codes 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 insurers 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. On December 20, 2019, the President signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act, or the LAB Act. The LAB Act delays by one year the reporting of payment data under PAMA for clinical laboratory diagnostic tests that are not advanced diagnostic laboratory tests. CDLT data for the collection period of January 1, 2019 through June 30, 2019, which was supposed to be reported in 2020, must now be reported between January 1, 2021 and March 31, 2021. Data reporting will then resume on a three-year cycle beginning in 2024. Under PAMA, as amended by the LAB Act, any reduction to a particular payment rate resulting from the new methodology is limited to 10% per test per year in 2020 and to 15% per test per year in each of the years 2021 through 2023.

Coverage Decisions

When deciding whether to cover a particular diagnostic test, private and government third-party payors generally consider whether the test is a medically necessary and, if so, whether the test will directly impact clinical decision making. For coverage, the testing method should be considered scientifically valid to identify the specific gene biomarker or gene mutation, and must have been demonstrated to improve clinical outcomes for the patient's condition. Coverage of a drug therapy and its companion diagnostic are usually validated by a NCCN category 1, 2A or 2B recommendation. 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 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, establish fee schedule rates, 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 rates for diagnostic tests furnished to Medicare beneficiaries in outpatient settings are the lesser of the amount billed, the local fee for a geographic area, or a national limit. Each year, the fee schedule is updated for inflation and could be modified by Congress in accordance with the CLFS rules and provisions. Medicaid programs generally pay for diagnostic tests based on a fee schedule, but reimbursement varies by geographic region.

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.

Organizational Structure

QIAGEN N.V. is the holding company for more than 50 consolidated subsidiaries, many of which have the primary function of distributing our products and services on a regional basis. Certain subsidiaries also have research and development or production activities. A listing of our significant subsidiaries and their jurisdictions of incorporation is included in Exhibit 8.1 to this Annual Report.

Description of Property

Our production and manufacturing facilities for consumable products are located in Germany, the United States and China. Our facilities for software development are located in the United States, Germany, Poland, Denmark 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 $118.0 million, $109.8 million and $90.1 million for 2019, 2018 and 2017, 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, Germantown, Maryland and Shenzhen, China. 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 786,000 square feet. Our most recent expansion to these facilities was in 2018 and included approximately 6,400 square feet of clean room space for Stat-DX integration. 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.

We lease facilities in Frederick, Maryland comprising 42,000 square feet for manufacturing, warehousing, distribution and research operations and also facilities in Beverly, Massachusetts with 44,000 square feet for enzyme manufacturing. Additionally, we have leased facilities in Redwood City, California with 12,700 square feet for digital insights and 19,000 square feet in Minden, Nevada for Service Solutions. We have shared service centers which lease facilities in Wroclaw, Poland (48,600 square feet) and Manila, Philippines (29,300 square feet). Additionally, we lease facilities in Shenzhen, China and Manchester, United Kingdom for research operations. 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.

Opportunities and Risks

QIAGEN's business, like that of any other company, involves significant opportunities and risks. Effective management is paramount in delivering sustainable value creation, and the central task of the leadership team. To sustain QIAGEN's growth, effective execution is crucial in the development and commercialization of new products; structure and implementation of acquisitions and strategic partnerships; and response to the wide variety of developments in markets where QIAGEN operates around the world. Managing opportunities and risks is an integral part of the corporate governance system in place throughout QIAGEN, not the task of one particular organizational unit. Management systems are in place to aggregate all risks and opportunities for review at the Managing Board and Supervisory Board levels of QIAGEN N.V., and these are reviewed on a routine basis. Based on our assessment at the end of 2019, we consider the opportunities and risks manageable and the survival of QIAGEN not in danger, the same position taken at year-end 2018. This assessment is supported by our strong balance sheet and the current business outlook, and further supported by the positive historical response to our external financing needs. As a result, QIAGEN has not sought an official rating by any of the leading rating agencies. We are confident in the future earnings strength of QIAGEN and have access to the resources to pursue value-creating business opportunities.

Opportunities

Our mission is to make improvements in life possible by capturing growth opportunities as genomic and molecular technologies disseminate across two customer classes: Molecular Diagnostics and Life Science, including Academia and Applied Testing and Pharma. Due to increased life expectancies worldwide and the dynamic growth of healthcare both in developed and emerging markets, the need for innovative diagnostics is increasing. Diagnostics offer proven benefits to improve healthcare outcomes, particularly the use of companion diagnostics in precision medicine, while still representing a small fraction of overall healthcare expenditures. Internal R&D activities of QIAGEN and partnerships with other companies present major opportunities to develop new products and improve existing ones across our portfolio of Sample to Insight solutions. We also continuously evaluate potential targeted acquisition opportunities to add new technologies or enter growing markets. All of these factors represent future growth opportunities for QIAGEN.

Senior management at QIAGEN focuses strategic attention on identifying and assessing opportunities as early as possible, taking actions to maximize the value of those opportunities and executing on initiatives to deliver business success. QIAGEN evaluates organic growth opportunities each year as part of its annual budget planning process, and during the year, especially in dynamically changing areas of the business portfolio. These evaluations are based on proposals for new products, services and technologies developed within QIAGEN. This cross-functional process involves a careful analysis of the market environment and competitive positioning, as well as factors such as

expected development timelines, regulatory processes and reimbursement issues, when evaluating organic opportunities. Business plans include information about the product or service to be developed, along with profiles on target customers and competitors, market size and barriers to entry. It also outlines the resources required for implementation. As part of this process, these plans are subjected to a uniform profitability analysis to determine the net present value of an investment and the opportunities to create value (as measured with QIAGEN Value Added, or QVA) and generate returns that exceed the Group's cost of capital after a multi-year period. The monitoring of growth initiatives is accomplished through regular reporting to the Supervisory Board on the status and progress of key initiatives during the year. Project management and the supporting central functions report directly to the Executive Committee.

Risk Factors

Risk Management:

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

QIAGEN is managed by a Managing Board and an independent Supervisory Board appointed by the General Meeting of Shareholders. One of the Managing Board's responsibilities is the oversight of the risk management system. The Managing Board has developed and implemented strategies, controls and mitigation measures to identify current and developing risks as part of the risk management system. These policies and procedures are embodied in our corporate governance, code of ethics and financial reporting controls and procedures. A variety of functional experts evaluate these business risks, attempting to mitigate and manage these risks on an ongoing basis.

Identified risks are subdivided into three types:

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

All identified risks are evaluated based on their likelihood of occurring and their potential impact (estimated in monetary terms) in disrupting our progress in achieving our business objectives. The overall risk management goal is to identify risks that could significantly threaten our success and to allow management on a timely basis the opportunity to successfully implement mitigation actions. The results of the risk assessment, and any updates, are reported to the Audit Committee of the Supervisory Board on a regular basis. A detailed risk reporting update is provided each quarter to the Audit Committee for specific risks that have been newly identified or have changed since the previous assessment. At least once on an annual basis, the Supervisory Board discusses the corporate strategy and business risks as well as the results of an assessment by the Managing Board and the Audit Committee of the structure and operations of the internal risk management and control systems, including any significant changes.

Our corporate governance structure is based on a strong framework that outlines the responsibilities of our Managing and Supervisory Boards (discussed in more detail in the "Corporate Governance" section below) and the function of the Audit Committee of the Supervisory Board (discussed in more detail in the "Corporate Governance" section below). We maintain adequate internal controls over financial reporting to ensure the integrity of financial reporting, which is described further in the "Corporate Governance" section below. Additionally, we have a Compliance Committee that consists of senior executives from various functional areas who are responsible for ensuring compliance with legal and regulatory requirements, as well as overseeing the communication of corporate policies, including our Code of Ethics as described further in the "Human Resources" section below.

Risk Types	
Base Business Risk	· Identification and monitoring of competitive business threats · Monitoring complexity of product portfolio · Monitoring dependence on key customers for single product groups · Reviewing dependence on individual production sites or suppliers · Evaluating purchasing initiatives, price controls and changes to reimbursements · Monitoring production risks, including contamination prevention, high-quality product assurance · Ensuring ability to defend against intellectual property infringements and maintain competitive advantage after expiration
Business Growth Risk	· Managing development and success of key R&D projects · Managing successful integration of acquisitions to achieve anticipated benefits
Underlying Business Risk	· Evaluating financial risks, including economic risks and currency rate fluctuations · Monitoring financial reporting risks, including multi-jurisdiction tax compliance · Reviewing possible asset impairment events · Assessing compliance and legal risks, including safety in operations and environmental hazard risks, compliance with various regulatory bodies and pending

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

Risks:

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

Rapid technological change and frequent new product introductions are typical in the markets we serve. Our success will depend in part on continuous, timely development and introduction of new products that address evolving market requirements. We believe successful new product introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product and are reluctant to switch after these efforts. To the extent that we fail to introduce new and innovative products, or such products suffer significant delays in development or are not accepted in the market, we may lose market share to our competitors that would be difficult or impossible to regain. An inability to successfully develop and introduce new products, for technological or other reasons, could reduce our growth rate or otherwise have an adverse effect on our business. In the past, we have experienced delays in the development and introduction of products, including regulatory approvals, or decisions to stop development of projects, and we may experience delays or make decisions to stop certain products in the future.

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

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

In the development of new products we may make significant investments in intellectual property and software solutions. These investments increase our fixed costs, resulting in higher operational costs in the short term that will negatively impact our gross profit and operating income until products potentially reach a minimum level of market acceptance. The expenses or losses associated with unsuccessful product development activities or lack of market acceptance of our new products could materially adversely affect our business, financial condition and results of operations.

Our continued growth depends significantly on the success of new products in the molecular testing markets we serve. Important new product programs underway include our modular medium-throughput QIAsymphony automation platform, QIAstat-Dx system for one-step, fully integrated molecular analysis of hard-to-diagnose syndromes, the high-throughput NeuMoDx 288 and mid-throughput NeuMoDx 96 fully integrated PCR automation systems, sample and assay technologies designed either for use either with QIAGEN instruments or for "universal" automation systems and instruments, and bioinformatics solutions to analyze and interpret complex genomic data. In addition, we are now developing next-generation systems for digital PCR, an emerging analytical technique in the life sciences, targeting a 2020 launch with fully-integrated solutions that simplify workflows and offer other advantages.

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

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

Our business has grown, with total net sales increasing to $1.53 billion in 2019 from $1.28 billion in 2015. We have made a series of acquisitions in recent years, including the acquisitions of N-of-One in January 2019, STAT-Dx Life, S.L. in 2018, and OmicSoft Corporation in 2017 to complement internal research and development activities. We intend to identify and acquire other businesses in the future that support our strategy to build on our global leadership position in Sample to Insight solutions focused on molecular testing. The successful integration of acquired businesses requires a significant effort and expense across all operational areas.

We continue to make investments to expand our existing business operations. These projects increase our fixed costs, resulting in higher operational costs in the short term that will negatively impact our gross profit and operating income until we more fully utilize the additional capacity of these facilities. In addition, we have invested in establishing and expanding shared service centers in Poland and the Philippines, opening new commercial operations in emerging markets to expand our geographic footprint, and implementing digitization of business processes to increase sales growth while also enhancing operational efficiencies. The expansion of our business and the addition of new personnel may place a strain on our management and operational systems. As we continue to upgrade our operating and financial systems, as well as expand the geographic presence of our operations, we intend to continue to assess the need to reallocate existing resources or hire new employees, as well as increased responsibilities for both existing and new management personnel.

Our future operating results will depend on our ability to continue to implement and improve our research, product development, manufacturing, sales and marketing and customer support programs, enhance our operational and financial control systems, expand, train and manage our employee base, integrate acquired businesses, and effectively address new issues related to our growth as they arise. There can be no assurance that we will be able to manage our recent or any future expansion or acquisitions successfully, and any inability to do so could have a material adverse effect on our results of operations.

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

During the past several years, we have acquired and integrated a number of companies through which we have gained access to new technologies, products and businesses that complement our internally developed product lines. In the future, we expect to acquire additional technologies, products or businesses to expand our operations. Acquisitions expose us to new operating and financial risks, including risks associated with the:

- assimilation of new products, technologies, operations, sites and personnel;
- integration and retention of fundamental personnel and technical expertise;
- application for and achievement of regulatory approvals or other clearances;
- diversion of resources from our existing products, business and technologies;
- generation of sales;
- implementation and maintenance of uniform standards and effective controls and procedures;
- exposure to pre-existing cyber security risks or compromise of acquired entities;
- maintenance of relationships with employees, customers and suppliers, and integration of new management personnel;
- issuance of dilutive equity securities;
- incurrence or assumption of debt and contingent liabilities;
- amortization or impairment of acquired intangible assets or potential businesses; and
- exposure to liabilities of and claims against acquired entities or personnel, including patent litigation.

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

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

Our results of operations could be materially affected by adverse general conditions in the global economy and financial markets.

The global outbreak of COVID-19 will have a significant impact on QIAGEN in 2020. Extraordinary demand has emerged for molecular technologies involved in testing for the new pathogen. However, the total impact is not predictable at this point, as the spike in demand is challenging the company's short-term capacity for certain products, while the pandemic also is disrupting broader economies and routine healthcare in 2020.

Potentially adverse changes that may come from the United Kingdom's exit from the European Union ("Brexit") are not well understood as the actual impact from Brexit will depend on many factors including the ability of both the United Kingdom and European Union authorities to provide a path forward with minimal disruption. In the near term we anticipate the largest potential exposures to be on supply chain with our United Kingdom based suppliers and the local operations for our domestic United Kingdom business and pharma development activities. There also is a risk of loss of revenue, penalties due to delayed deliveries and currency losses, or other unforeseen costs which would negatively impact margins.

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

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

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

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

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

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

Further, the ability of many of our customers to successfully market their products depends in part on the extent to which reimbursement for the costs of these products is available from governmental health administrations, private health insurers and other organizations. Governmental and other third-party payors are increasingly seeking to contain healthcare costs and to reduce the price of medical products and services. For example, in 2010, the Patient Protection and Affordable Care Act, or ACA, was enacted with the goal of expanding coverage, increasing quality of care and reducing costs through payment innovation, among other things. With evolving political realities in the United States, including divergent efforts by the Trump Administration and members of Congress, certain sections of the ACA have not been fully implemented and the direction of healthcare policy is unpredictable. Uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. In accordance with the Protecting Access to Medicare Act of 2014 (PAMA), the Centers for Medicare & Medicaid Services calculate 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 Clinical Laboratory Fee Schedule (CLFS). If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

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

Our customers include researchers at pharmaceutical and biotechnology companies, academic institutions, and government and private laboratories. Fluctuations in the research and development budgets of these organizations could have a significant adverse effect on demand for our products. Research and development budgets are affected by changes in available resources, the mergers of pharmaceutical and biotechnology companies, changes in spending priorities and institutional budgetary policies. Our results of operations could be adversely affected by any significant decrease in expenditures for life sciences research and development by pharmaceutical and biotechnology companies, academic institutions, and government and private laboratories. In addition, short-term changes in administrative, regulatory or purchasing-related procedures can create uncertainties or other impediments that can have an adverse impact on our results of operations.

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

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

Competition could reduce our sales.

The markets for most of our products are very competitive. Competitors may have significant advantages in financial, operational, sales and marketing resources as well as experience in research and development. These competitors may have developed, or could develop in the future, new technologies that compete with our products or even render our products obsolete. Some competitors may obtain regulatory approval from the FDA or similar non-U.S. authorities and market approved products. Our competitors' development of alternative products offering superior technology, greater cost-effectiveness or regulatory approval could have a material adverse effect on our sales and results of operations.

The growth of our business depends in part on the continued conversion of users from competitive products to our sample and assay technologies and other solutions. Lack of conversion could have a material adverse effect on our sales and results of operations.

It can be difficult for users of our products to switch from their current supplier of a particular product, primarily due to the time and expense required to properly integrate new products into their operations. As a result, if we are unable to be the first to develop and supply new products, our competitive position may suffer, resulting in a material adverse effect on our sales and results of operations.

For our commercial clinical assays, we often compete with solutions developed by our laboratory customers, and driving conversion from such laboratory-developed tests (LDTs) to commercial diagnostics assays can be challenging.

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

We and our customers operate in a highly regulated environment characterized by frequent changes in the governing regulatory framework. Genetic research activities and products commonly referred to as "genetically engineered" (such as certain food and therapeutic products) are subject to extensive governmental regulation in most developed countries, especially in the major markets for pharmaceutical and diagnostic products such as the European Union, the U.S., China and Japan. In recent years, several highly publicized scientific events (notably in genomic research, gene editing and cloning) have prompted intense public debates on the ethical, philosophical and religious implications of an unlimited expansion in genetic research and the use of products emerging from this research. As a result of this debate, some key countries may increase or establish regulatory barriers, which could adversely affect demand for our products and prevent us from fulfilling our growth expectations. Furthermore, there can be no assurance that any future changes in applicable regulations will not require further expenditures or an alteration, suspension or liquidation of our operations in certain areas, or even in their entirety.

Changes in the existing regulations or adoption of new requirements or policies could adversely affect our ability to sell our approved or cleared products or to seek approvals for new products in other countries around the world. Sales of certain products now in development may be dependent upon us successfully conducting pre-clinical studies, clinical trials and other tasks required to gain regulatory approvals and meet other requirements from the FDA in the U.S., and regulatory agencies in other countries. If we are not able to meet the applicable requirements, we will not be able to commercialize our products and tests, which will have a material adverse effect on our business.

Several of our key products and programs are medical devices that are subject to extensive regulation by the FDA under the U.S. Food, Drug and Cosmetic Act. We plan to apply for FDA clearance or approval of additional products in the future. Regulatory agencies in other countries also have medical device and IVD approval requirements that are becoming more extensive. These regulations govern most commercial activities associated with medical devices, including indications for the use of these products as well as other aspects that include product development, testing, manufacturing, labeling, storage, record-keeping, advertising and promotion. Compliance with these regulations is expensive and time-consuming.

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

Some of our products are sold for research purposes in the U.S. We do not promote these products for clinical diagnostic use, and they are labeled "For Research Use Only" (RUO) or "for molecular biology applications." If the FDA were to disagree with our designation of a product as having RUO status, we could be forced to stop selling it until appropriate regulatory clearance or approval has been obtained.

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

Our effective tax rate reflects the benefit of some income being partially exempt from income taxes due to various intercompany operating and financing activities. The benefit also derives from our global operations, where income or loss in some jurisdictions is taxed at rates higher or lower than The Netherlands' statutory rate of 25%. Changes in tax laws or their application with respect to matters such as changes in tax rates, transfer pricing and income allocation, utilization of tax loss carryforwards, intercompany dividends, controlled corporations, and limitations on the deductibility of interest and foreign related-party expenses, and changes to tax credit mechanisms, could increase our effective tax rate and adversely affect our results of operations and limit our ability to repurchase our Common Shares without experiencing adverse tax consequences. The increased tax burden as a result of changes in law may adversely affect our results of operations. Additionally, if our tax positions are challenged by tax authorities or other governmental bodies, such as the European Commission, we could incur additional tax liabilities, which could have an adverse effect on our results of operations or financial flexibility.

We are subject to risks associated with patent litigation.

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

We rely on collaborative commercial relationships to develop and/or market some of our products.

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

Our Precision Medicine business includes projects with pharmaceutical and biotechnology companies to co-develop companion diagnostics paired with drugs that those companies either market currently or are developing for future use. The success of these co-development programs, including regulatory approvals for the companion diagnostics, depends upon the continued commitment of our partners to development of their drugs, the outcome of clinical trials for the drugs and diagnostics, and regulatory approvals of the tests and drugs. In addition, the future level of sales for companion diagnostics depends to a high degree on the commercial success of the related medicines for which the tests have been designed. More companion diagnostics would be sold in combination with a widely prescribed drug than one with limited use.

The successful marketing of QIAGEN products, in some cases, depends on commercial relationships such as joint ventures or distributorships, particularly in emerging markets where we partner with local companies to augment our less-established commercial relationships and infrastructure. The continued commitment of our partners to these ventures, as well as the management of the commercial efforts, will influence QIAGEN's sales and profitability in these markets.

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

Our top seven emerging markets are Brazil, Russia, India, China, South Korea, Mexico and Turkey, which together accounted for approximately 16% of total sales in 2019. We expect to continue to focus on expanding our business in these or other fast-growing markets, including those in the Middle East and Asia. In addition to the currency and operating risks described above, our international operations are subject to a variety of risks that include those arising out of the economy, political outlook, language and cultural barriers in countries where we have operations or do business. In many of these emerging markets, we may be faced with several risks that are more significant than in other countries in which we have a history of doing business. These risks include economies that may be dependent on only a few products and are therefore subject to significant fluctuations, weak legal systems which may affect our ability to enforce contractual rights, exchange controls, unstable governments, and privatization or other government actions affecting the flow of goods and currency. In conducting our business, we move products from one country to another and may provide services in one country from a subsidiary located in another country. Accordingly, we are vulnerable to abrupt changes in customs and tax regimes that could have significant negative impacts on our results of operations.

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

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

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

We rely heavily on communications and information systems to conduct our business. In the ordinary course of business, we collect and store sensitive data, including our own intellectual property and other proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, in our data centers and on our networks. Our operations rely on the secure processing, storage and transmission of confidential and other information on our computer systems and networks. We are transforming to a digital, cloud-leveraging organization, which places our assets, customer data, and personally identifiable data at a higher risk than in previous years. We have made significant investments to ensure our employees are aware of cyber security risks facing our company and how to prevent data breaches. We have modernized our cyber security tools, and are continually modernizing our cyber security processes, in an attempt to keep pace with evolving cyber security risks. In spite of our efforts, we are unable to completely eliminate these risks and occasionally experience minor cyber security incidents. External phishing emails (occurring outside of our computer services) are a growing threat that our customers are facing. These emails could lead to the disclosing of intellectual property or personally identifiable information, which could lead to financial harm or reputational damage. While our cyber security team works diligently with our employees around the world, as well as with our customers, to mitigate these threats by helping to identify and analyze phishing emails, we cannot guarantee that sensitive data will not be lost or stolen.

A breach in cyber security due to unauthorized access to our computer systems or misuse could include the misappropriation of assets or sensitive information, the corruption data or other operational disruption. Failures to our computer systems and networks could be caused by internal or external events, such as incursions by intruders or hackers, computer viruses, failures in hardware or software, or cyber terrorists. If we do experience a breach or failure of our systems, we could experience potentially significant operational delays resulting from the disruption of systems, loss due to theft or misappropriation of assets or data, or negative impacts from the loss of confidential data or intellectual property. We may face significant liability in the event any of the personal information we maintain is lost or otherwise subject to misuse or other wrongful use, access or disclosure. Further, we could experience negative publicity resulting in reputation or brand damage with customers or partners.

Additionally, we are subject to privacy and data security laws across multiple jurisdictions, including those relating to the storage of health information, which are complex, overlapping and rapidly evolving. For example, the California Consumer Privacy Act of 2018, which took effect on January 1, 2020, imposes expansive new requirements and protections upon the processing of personal data, aimed at giving California consumers more visibility and control over their personal information There are also 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. We implemented the requirements set forth by the European Union General Data Protection Regulation (GDPR), which took effect on May 25, 2018. As our activities continue to evolve and expand, we may be subject to additional laws which impose further restrictions on the transfer, access, use, and disclosure of health and other personal information which may impact our business either directly or indirectly. A 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.

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

Given that we currently market our products throughout the world, a significant portion of our business is conducted in currencies other than the U.S. dollar, our reporting currency. As a result, fluctuations in value relative to the U.S. dollar of the currencies in which we conduct our business have caused and will continue to cause foreign currency transaction gains and losses. Foreign currency transaction gains and losses arising from normal business operations are charged against earnings in the period when incurred. Due to the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we cannot predict the effects of future exchange rate fluctuations. While we may engage in foreign exchange hedging transactions to manage our foreign currency exposure, there can be no assurance that our hedging strategy will adequately protect our operating results from the effects of future exchange rate fluctuations.

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

Our business involves operations around the world. Our consumable manufacturing facilities are located in Germany, the U.S. and China. We have established sales subsidiaries in numerous countries and our products are sold through independent distributors serving more than 40 additional countries. Our global footprint exposes us to unforeseen events, such as the January 2020 eruption of the Taal volcano in the Philippines or the December 2019 outbreak of COVID-19 in China. Our facilities may be harmed by unforeseen events, and in the event that we or our customers are affected by a disaster, we may experience delays or reductions in sales or production, increased costs, or may be required to identify alternate suppliers and/or rely on third-party manufacturers.

To the extent that our suppliers are impacted by a natural disaster or other disruption, we may experience periods of reduced production. Any unexpected interruptions in our production capabilities may lead to delayed or lost sales and may adversely affect our results of operations for the affected period.

In addition, to the extent we temporarily shut down any facility following such an unforeseen event, we may experience disruptions in our ability to manufacture or ship products to customers or otherwise operate our business. Many of our products are manufactured in a single location and we may experience adverse effects to the extent these manufacturing operations are disrupted. While our global operations give us the ability to ship product from alternative sites, we may not be able to do so because our customers' facilities are shut down or the local logistics infrastructure is not functioning, and our sales will suffer.

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

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

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

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

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

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

Although we have not experienced any difficulties attracting or retaining management and scientific staff, our ability to recruit and retain qualified, skilled employees will continue to be critical to our success. Given the intense competition for experienced scientists and managers among pharmaceutical and biotechnology companies, as well as academic and other research institutions, there can be no assurance that we will be able to attract and retain employees critical to our success on acceptable terms. Initiatives to expand QIAGEN will also require additional employees, including management with expertise in areas such as research and development, manufacturing, digitization, sales and marketing, and the development of existing managers to lead a growing organization. The failure to recruit and retain qualified employees, or develop existing employees, could have a material adverse impact on our results of operations. We may face difficulties in hiring and retaining qualified personnel following our March 3, 2020 announcement of the proposed merger with Thermo Fisher Scientific Inc.

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

The markets we serve are typically characterized by a high percentage of purchase orders being received in the final few weeks or days of each quarter. Although this varies from quarter to quarter, many customers make a large portion of their purchase decisions late in each quarter, in particular because they receive new information during this period on their budgets and requirements. Additionally, volatility in the timing of revenue from companion diagnostic partnerships can be difficult to predict. As a result, even late in each quarter, we cannot predict with certainty whether our sales forecasts for the quarter will be achieved.

Historically, we have been able to rely on the overall pattern of customer purchase orders during prior periods to project with reasonable accuracy our anticipated sales for the current or coming quarters. However, if customer purchasing trends during a quarter vary from historical patterns as may occur with changes in market and economic conditions our quarterly financial results could deviate significantly from our projections. As a result, our sales forecasts for any given quarter may prove not to be accurate. We also may not have sufficient, timely information to confirm or revise our sales projections for a specific quarter. If we fail to achieve our forecasted sales for a particular quarter, the value of our Common Shares could be significantly affected.

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

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

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

The Financial Conduct Authority of the United Kingdom plans to phase out the London Interbank Offered Rate (LIBOR) by the end of 2021. Presently, we do hold debt and derivative instruments that use LIBOR. While certain agreements do contain language for the determination of interest rates in the event the LIBOR rate is not available, changes to these agreements may be required, and we could be negatively impacted by any newly determined alternative benchmark.

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

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

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

We currently anticipate that our short-term capital requirements will be satisfied by cash flow from our operations and/or cash on hand. As of December 31, 2019, we had outstanding long-term debt of $1.7 billion, of which $285.2 million was current. We may need to refinance all or part of these liabilities before or at their contractual maturities.

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

The accounting for the cash convertible notes we have issued will result in recognition of interest expense significantly greater than the stated interest rate of the notes and may result in volatility to our Consolidated Statements of Income.

We will settle any conversions of the Cash Convertible Notes described under the heading “Other Factors Affecting Liquidity and Capital Resources” elsewhere in this report, entirely in cash. Accordingly, the conversion option that is part of the Cash Convertible Notes will be accounted for as a derivative pursuant to accounting standards relating to derivative instruments and hedging activities. Refer to Note 14 "Derivatives and Hedging" and Note 16 "Lines of Credit and Debt", of the Notes to Consolidated Financial Statements. In general, this resulted in an initial valuation of the conversion option separate from the debt component of the Cash Convertible Notes, resulting in an original issue discount. The original issue discount will be accreted to interest expense over the term of the Cash Convertible Notes, which will result in an effective interest rate reported in our financial statements significantly in excess of the stated coupon rates of the Cash Convertible Notes. This accounting treatment will reduce our earnings. For each financial statement period after the issuance of the Cash Convertible Notes, a gain (or loss) will be reported in our financial statements to the extent the valuation of the conversion option changes from the previous period. The Call Options issued in connection with the Cash Convertible Notes will also be accounted for as derivative instruments, substantially offsetting the gain (or loss) associated with changes to the valuation of the conversion option. This may result in increased volatility to our results of operations.

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

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

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

At December 31, 2019, our consolidated balance sheet reflected $2.1 billion of goodwill and $632.4 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles (U.S. GAAP) require us to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment review often cannot be done at the level of the individual asset and it must instead be applied to a group of assets. For the purpose of our annual goodwill impairment testing based on the current circumstances of how we manage our business, this group of assets is the Company as a whole. If we determine that any of our goodwill or intangible assets were impaired, we will be required to take an immediate charge to earnings and our results of operations could be adversely affected.

Our strategic equity investments may result in losses.

We have made, and may continue to make, strategic investments in businesses as opportunities arise. We periodically review the carrying value of these investments for impairment, considering factors that include the most recent stock transactions, book values from the most recent financial statements, and forecasts and expectations of the investee. The results of these valuations may fluctuate due to market conditions and other conditions over which we have no control.

Estimating the fair value of non-marketable equity investments in life science companies is inherently subjective. If actual events differ from our assumptions and unfavorable fluctuations in the valuations of the investments are indicated, we could be required to write down the investment. This could result in future charges on our earnings that could materially adversely affect our results of operations. It is uncertain whether or not we will realize any long-term benefits from these strategic investments.

Doing business internationally creates certain risks.

Our business involves operations in several countries outside of the U.S. Our consumable manufacturing facilities are located in Germany, China and the U.S. We source raw materials and subcomponents to manufacture our products from different countries. We have established sales subsidiaries in many countries. In addition, our products are sold through independent distributors serving more than 40 other countries. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. We have invested heavily in computerized information systems in order to manage more efficiently the widely dispersed components of our operations. If we fail to coordinate and manage these activities effectively, our business and results of operations will be adversely affected.

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

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

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

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

Our success depends to a large extent on our ability to develop proprietary products and technologies and to establish and protect our patent and trademark rights in these products and technologies. As of December 31, 2019, we owned 352 issued patents in the United States, 275 issued patents in Germany and 1,700 issued patents in other major industrialized countries. In addition, at December 31, 2019, we had 558 pending patent applications, and we intend to file applications for additional patents as our products and technologies are developed. The patent positions of technology-based companies involve complex legal and factual questions and may be uncertain, and the laws governing the scope of patent coverage and the periods of enforceability of patent protection are subject to change. In addition, patent applications in the United States are maintained in secrecy until patents issue, and publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months. Therefore, no assurance can be given that patents will issue from any patent applications that we own or license, or if patents do issue, that the claims allowed will be sufficiently broad to protect our technology. In addition, no assurance can be given that any issued patents that we own or license will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide us competitive advantages. Further, as issued patents expire, we may lose some competitive advantage as others develop competing products and as a result, we may lose revenue.

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

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

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

Our business exposes us to potential product liability.

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

We are subject to various laws and regulations generally applicable to businesses in the different jurisdictions in which we operate, including laws and regulations applicable to the handling and disposal of hazardous substances. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could have a material adverse impact on us.

Our operating results may vary significantly from period to period and this may affect the market price of our Common Shares.

Our operating results may vary significantly from quarter to quarter, and also year to year, since they are dependent upon a broad range of factors that include demand for our products, the level and timing of customer research budgets and commercialization efforts, the timing of government funding budgets of our customers, the timing of our research and development activities and related regulatory approvals, the impact of sales and marketing expenses, restructuring activities, introduction of new products by us or our competitors, competitive market conditions, exchange rate fluctuations and general economic conditions. Our expense levels are based in part on our expectations as to future sales trends. As a result, sales and earnings may vary significantly from quarter to quarter or from year to year, and actual sales and earnings results in any one period will not necessarily be indicative of results to be anticipated in subsequent periods. Our results may also fail to meet or exceed the expectations of securities analysts or investors, which could cause a decline in the market price of our Common Shares.

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

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

Our Common Shares may have a volatile public trading price.

The market price of our Common Shares since our initial public offering in September 1996 has increased significantly and been highly volatile. Beginning January 10, 2018, our shares are listed on the New York Stock Exchange (NYSE). Before that, our shares were listed on the NASDAQ through January 9, 2018. In the last two years, the price of our Common Shares has ranged from a high of $43.16 to a low of $25.04. On the Frankfurt Stock Exchange our Common Shares have ranged from a high of €39.19 to a low of €22.54 during the last two years. In addition to overall stock market fluctuations, factors that may have a significant impact on the price of our Common Shares include:

- announcements of technological innovations or the introduction of new products by us or our competitors;
- developments in our relationships with collaborative partners;
- quarterly variations in our operating results or those of our peer companies;
- changes in government regulations, tax laws or patent laws;
- developments in patent or other intellectual property rights;
- developments in government spending budgets for life sciences-related research;
- general market conditions relating to the diagnostics, applied testing, pharmaceutical and biotechnology industries; and
- impact from foreign exchange rates.

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

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

QIAGEN has not paid an annual dividend since its inception, nor intends to implement one at this time. At the same time, in January 2017 we completed a synthetic share repurchase that combined a direct capital repayment with a reverse stock split. Although we do not anticipate paying any cash dividends on a regular basis, the distribution of any cash dividends through another synthetic share repurchase in a currency other than the U.S. dollar will be subject to the risk of foreign currency transaction losses. Investors should not invest in our Common Shares if they are seeking dividend income; the only return that may be realized through investing in our Common Shares would be through an appreciation in the share price.

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

QIAGEN has conducted share repurchase programs in the past through open-market transactions. Additionally, in January 2017, we completed a synthetic share repurchase that combined a direct capital repayment with a reverse stock split. The transaction was announced in August 2016 and involved an approach used by various large, multinational Dutch companies to provide returns to all shareholders in a faster and more efficient manner than traditional open-market purchases. $243.9 million was returned to shareholders through the transaction, which reduced the total number of issued common shares by approximately 3.7% or 8.9 million shares as of January 31, 2017.

The purpose of our share repurchases has been to hold the shares in treasury in order to satisfy obligations from exchangeable debt instruments, warrants and/or employee share-based remuneration plans and thus to reduce dilution to existing holders of our Common Shares. In 2019, we began net share withholding on the vesting of stock-based awards and as a result, fewer shares are issued than the number of awards outstanding. We may decide not to continue such programs in the future, our covenants with lenders may limit our ability to use available cash to do so, or the market price of our Common Shares may make such repurchases less desirable. In any of these cases, holders of our Common Shares may suffer dilution from conversion of our indebtedness or issuance of shares pursuant to employee remuneration plans that would otherwise be at least partially offset by repurchased shares.

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

Any future sale or issuance of a substantial number of our Common Shares in the public market, or any perception that a sale may occur, could adversely affect the market price of our Common Shares. Under Dutch law, a company can issue shares up to its authorized share capital provided for in its Articles of Association. Pursuant to our Articles of Association, our authorized share capital amounts to EUR 9.0 million, which is divided into 410.0 million common shares, 40.0 million financing preference shares and 450.0 million preference shares, with all shares having a EUR 0.01 par value. As of December 31, 2019, a total of approximately 227.8 million Common Shares were outstanding along with approximately 6.0 million additional shares reserved for issuance upon exercise or release of outstanding stock options and awards, of which 0.8 million were vested. A total of approximately 15.7 million Common Shares are reserved and available for issuances under our stock plans as of December 31, 2019, including the shares subject to outstanding stock options and awards. The majority of our outstanding Common Shares may be sold without restriction, except shares held by our affiliates, which are subject to certain limitations on resale. Additionally, the Warrants issued in connection with the Cash Convertible Notes Call Spread Overlays cover an aggregate of 31.1 million shares of our common stock (subject to customary adjustments under certain circumstances).

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

We may be classified as a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes if certain tests are met. Our treatment as a PFIC could result in a reduction in the after-tax return to holders of Common Shares and would likely cause a reduction in the value of these shares. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to our U.S. shareholders. We would be considered a PFIC with respect to a U.S. shareholder if for any taxable year in which the U.S. shareholder held the Common Shares, either (i) 75% or more of our gross income for the taxable year is passive income; or (ii) the average value of our assets (during the taxable year) which produce or are held for the production of passive income is at least 50% of the average value of all assets for such year. Based on our income, assets and activities, we do not believe

that we were a PFIC for U.S. federal income tax purposes for our taxable year ended December 31, 2019, and do not expect to be a PFIC for the current taxable year or any future taxable year. No assurances can be made, however, that the Internal Revenue Service will not challenge this position or that we will not subsequently become a PFIC.

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

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

Certain other provisions of our Articles allow us, under certain circumstances, to prevent a third party from obtaining a majority of the voting control of our Common Shares through the issuance of Preference Shares. Pursuant to our Articles and the resolution adopted by our General Meeting of Shareholders, our Supervisory Board is entitled to issue Preference Shares in case of an intended takeover of our company by (i) any person who alone or with one or more other persons, directly or indirectly, have acquired or given notice of an intent to acquire (beneficial) ownership of an equity stake which in aggregate equals 20% or more of our share capital then outstanding or (ii) an "adverse person" as determined by the Supervisory Board. If the Supervisory Board opposes an intended takeover and authorizes the issuance of Preference Shares, the bidder may withdraw its bid or enter into negotiations with the Managing Board and/or Supervisory Board and agree on a higher bid price for our Shares.

In 2004, we granted an option to the Stichting Preferente Aandelen QIAGEN, or the Foundation (Stichting), subject to the conditions described in the paragraph above, which allows the Foundation to acquire Preference Shares from us. The option enables the Foundation to acquire such number of Preference Shares as equals the number of our outstanding Common Shares at the time of the relevant exercise of the option, less one Preference Share. When exercising the option and exercising its voting rights on these Preference Shares, the Foundation must act in our interest and the interests of our stakeholders. The purpose of the Foundation option is to prevent or delay a change of control that would not be in the best interests of our stakeholders. An important restriction on the Foundation's ability to prevent or delay a change of control is that a public offer must be announced by a third party before it can issue (preference or other) protective shares that would enable the Foundation to exercise rights to 30% or more of the voting rights without an obligation to make a mandatory offer for all shares held by the remaining shareholders. In addition, the holding period for these shares by the Foundation is restricted to two years, and this protective stake must fall below the 30% voting rights threshold before the two-year period ends. Notwithstanding the foregoing, in connection with the Business Combination Agreement that we entered into with Thermo Fisher Scientific Inc. (Thermo) on March 3, 2020 (BCA), we and the Foundation have agreed that (i) the Foundation shall not exercise the option in a way that would reasonably be expected to adversely affect the timely consummation of the acquisition contemplated by the BCA, unless and until the BCA has been terminated, (ii) if the Foundation exercises the option during the term of the BCA, the Foundation shall not exercise its voting rights as a shareholder in a manner that would reasonably be expected to adversely affect the timely consummation of the acquisition, unless and until the BCA has been terminated, (iii) the option shall be terminated subject only to the closing of the public tender offer (the "Closing") and (iv) to the extent any Preference Shares would be held by the Foundation as of the Closing, the Foundation shall transfer such shares to the wholly owned acquisition subsidiary of Thermo (Offeror) under the obligation for the Offeror to pay a cash consideration equal to the aggregate capital paid up on such Preference Shares plus any accrued dividends and to indemnify the Foundation for any claim by us.

Management Report

Performance Review

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

Results of Operations

Overview

We are a leading global provider of Sample to Insight solutions to transform biological materials into valuable molecular insights. QIAGEN sample technologies isolate and process DNA, RNA and proteins from any biological sample, such as blood or tissue. Assay technologies make these biomolecules visible and ready for analysis, such as identifying the DNA of a virus or a mutation of a gene. Digital insights integrate software and cloud-based resources to interpret increasing volumes of biological data and report relevant, actionable insights. Our automation solutions tie these together in seamless and cost-effective molecular testing workflows.

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

- **Molecular Diagnostics** - healthcare providers engaged in many aspects of patient care requiring accurate diagnosis and insights to guide treatment decisions in oncology, infectious diseases and immune monitoring. Includes Precision Medicine and companion diagnostics.
- **Life Sciences** - customers including government, biotechnology companies and researchers who utilize molecular testing and technologies who are generally served by public funding including areas such as medicine and clinical development efforts, forensics and exploring the secrets of life. Includes Pharma, Academia and Applied Testing customers.

We market products in more than 130 countries, mainly through subsidiaries in markets we believe have the greatest sales potential in Europe, Asia, the Americas and Australia. We also work with specialized independent distributors and importers. As of December 31, 2019, we employed approximately 5,100 people in more than 35 locations worldwide.

Recent Acquisitions

We have made a number of strategic acquisitions and implemented other strategic transactions aiming to achieve market-leading positions with innovative technologies in high-growth areas of molecular diagnostics and research. These transactions have enhanced our product offerings and technology platforms, as well as our geographic footprint. They include:

- In January 2019, QIAGEN began developing next-generation systems for digital PCR and acquired the digital PCR assets of Formulatrix, Inc., a developer of laboratory automation solutions. We expect to begin commercializing fully integrated digital PCR solutions in 2020, combining QIAGEN technologies and automation with the Formulatrix assets we acquired. Known as QIAcuity, the system will offer highly automated workflows, quicker time-to-result, and higher multiplexing and throughput flexibility than current digital PCR platforms. Digital PCR is one of the fastest-growing molecular testing applications in the life sciences industry. QIAGEN paid Formulatrix $125 million in cash upon closing and agreed to future milestone payments of approximately $136 million in 2020.
- Also in January 2019, QIAGEN acquired N-of-One, Inc., a pioneer in molecular oncology decision support services, to strengthen our bioinformatics leadership in clinical NGS interpretation. The acquisition broadened the QIAGEN Digital Insights offering of software, content and service-based solutions. N-of-One's services and content have been integrated into QIAGEN Clinical Insights (QCI), adding medical interpretation and real-world evidence insights. The N-of-One somatic cancer database, drawing upon more than 125,000 anonymized patient samples, has increased QIAGEN's lead as the provider of the industry's largest genomics knowledge base.
- In September 2018, QIAGEN announced a strategic partnership with NeuMoDx Molecular, Inc. to commercialize next-generation, fully integrated automation systems for PCR testing. The NeuMoDx 288 (high-throughput version) and NeuMoDx 96 (mid-throughput) systems help clinical laboratories process increasing molecular test volumes and deliver more rapid diagnostic insights. QIAGEN is initially distributing NeuMoDx systems and consumables in Europe and other markets outside the United States. The companies entered a merger agreement whereby QIAGEN will acquire remaining NeuMoDx shares that it does not currently own at a price of approximately $234 million (QIAGEN currently owns 19.9% of NeuMoDx), subject to the achievement of regulatory and operational milestones, by mid-2020.
- In April 2018, QIAGEN acquired STAT-Dx, a privately held company, and launched QIAstat-Dx, a next-generation multiplex PCR system developed by STAT-Dx, in Europe. The novel QIAstat-Dx system enables fast, cost-effective and flexible syndromic testing from Sample to Insight. The first two CE-IVD marked assays provide differential diagnosis of serious respiratory and gastrointestinal infections. In May 2019, we received FDA clearance and launched QIAstat-Dx in the United States with the respiratory panel. A broad menu of tests is under development in infectious disease, oncology and other areas. QIAGEN acquired STAT-Dx for approximately $149 million in cash and additional future payments of up to about $44 million based on the achievement of regulatory and commercial milestones.

Our financial results include the impacts of recent acquisitions from their effective dates.

NGS portfolio orientation and measures to prioritize resource allocation

In October 2019, QIAGEN announced a new orientation for its NGS-related activities that focuses development activities on maximizing the new Illumina partnership for IVD solutions, as well as expanding QIAGEN's offering of universal NGS consumables solutions for use with any sequencer. QIAGEN intends to continue supporting and servicing customers of the GeneReader NGS System, which is commercialized worldwide as a complete system for the processing of smaller targeted gene panels. However, QIAGEN discontinued development for new NGS instruments. Additionally, QIAGEN began implementing a set of initiatives to shift its Global Operations organization to a regional manufacturing structure and to expand the scope of activities at QIAGEN Business Services (QBS) centers in Wroclaw, Poland, and Manila, Philippines. QIAGEN currently anticipates further pre-tax charges of about $15-23 million in 2020 for these measures.

We determined that we operate as one business segment in accordance with ASC Topic 280, Segment Reporting. Our chief operating decision maker (CODM) makes decisions on business operations and resource allocation based on evaluations of the QIAGEN Group as a whole. Considering acquisitions made during 2019 together with recent changes in our management, we determined that we still operate as one business segment. We provide certain revenue information by customer class to allow better insight into our operations. This information is estimated using certain assumptions to allocate revenue among the customer classes.

Year Ended December 31, 2019, Compared to 2018

Net Sales

In 2019, net sales grew 2% to $1.53 billion compared to $1.50 billion in 2018 reflecting growth in consumables and related revenues which more than offset lower instrument revenues. Consumable and related revenues includes the contributions from our January 2019 acquisition of N-of-One, which provided net sales of approximately $5.0 million in 2019. We experienced increases across consumables and related revenues (+3% / 89% of sales) due to strong sales of the QuantiFERON-TB test as well as gains within the Life Sciences customer classes. This more than outweighed decreases across the instruments portfolio (-8% / 11% of sales) including lower sales of platforms for assay technologies and the GeneReader NGS Systems despite higher placements of the QIAcube Connect, QIASymphony and QIAstat-Dx systems. Net sales were negatively impacted by two percentage points from adverse currency movements against the U.S. dollar.

Customer classes: An overview of net sales by product category and customer class:

Net sales by product category and customer class

	Year ended December 31, 2019		
	Sales (In $ m)	% change	% of sales
Consumables and related revenues	$ 1,354	+3%	89%
Instruments	$ 172	-8%	11%
Molecular Diagnostics[1]	$ 737	+1%	48%
Life Sciences	$ 789	+2%	52%
Academia / Applied Testing	$ 487	+2%	32%
Pharma	$ 302	+4%	20%

(1) Includes companion diagnostic co-development revenues ($42 million, -28%).

Molecular Diagnostics grew 1% and represented 48% of sales in 2019. Molecular Diagnostics sales were adversely affected by three percentage points of adverse currency movements compared to 2018. Sales in 2019 included gains in consumables, in particular for the QuantiFERON-TB test compared to 2018 that was partially offset by significantly lower revenues from companion diagnostic co-development projects and instruments.

During 2019, Life Sciences sales grew 2% and reflected 52% of sales, while currency movements adversely impacted this customer class by three percentage point compared to 2018. Increased demand in consumables and related revenues across this customer class more than offset weaker instrument sales, which were affected by the focus on a new generation of products being prepared for launch and led by the new version of QIAcube Connect. Results for 2019 also absorbed the adverse effect of the April 2018 divestment of the Applied Testing veterinary testing assay portfolio.

Net sales by geographic region

	Year ended December 31, 2019		
	Sales (In $ m)	% change	% of sales
Americas	$ 722	+4%	47%
Europe / Middle East / Africa	$ 487	-1%	32%
Asia-Pacific / Japan	$ 314	0%	21%

Top 7 emerging markets: Brazil, Russia, India, China, South Korea, Mexico and Turkey ($250 million, +2%, 16% of sales)

Rest of world represented less than 1% of net sales.

The Americas led the geographic regions with 4% sales growth in 2019 with continued improvements within Life Sciences and overall gains in the United States, Brazil and Mexico against a decline in Canada. The Asia-Pacific / Japan region in 2019 was flat due primarily to the weaker results in China and Japan against gains in India. The EMEA region experienced a 1% decline due in part to declines in France and Italy against improving trends in Germany, Turkey and the United Kingdom.

Gross Profit

Gross profit was $1.01 billion, or 66% of net sales, in 2019, compared with $1.00 billion, or 67% of net sales, in 2018. Generally, our consumables and related products have a higher gross margin than our instrumentation products and service arrangements. Fluctuations in the sales levels of these products and services can result in changes in gross margin between periods. The growth in consumables and related revenue during 2019 contributed favorably to the margin, which was negatively impacted by higher amortization expenses related to developed technology and patent and license rights that were acquired in business combinations or asset acquisitions. The amortization expense on acquisition-related intangibles within cost of sales increased to $71.5 million in 2019 from $56.7 million in 2018. The increase was due to the asset acquisition from Formulatrix as further discussed in Note 5 "*Acquisitions and Divestitures*". We expect that our acquisition-related intangible amortization will increase as a result of further acquisitions in the future.

Research and Development

Research and development expenses fell by 3% to $157.4 million (10% of net sales) in 2019, from $161.9 million (11% of net sales) in 2018. The net decrease reflected higher investments in QIAstat-Dx and the planned launch of a digital PCR system against the significant reduction in costs following the decision to discontinue development of NGS-related instrument systems. As we continue to discover, develop and acquire new products and technologies, we expect to incur additional expenses related to facilities, licenses and employees engaged in research and development. Overall, research and development costs are expected to increase as a result of seeking regulatory approvals, including U.S. FDA Pre-Market Approval (PMA), U.S. FDA 510(k) clearance and EU CE approval of certain assays or instruments, but to decline as a percentage of sales in 2020 compared to 2019.

Sales and Marketing

Sales and marketing expenses were essentially unchanged at $391.9 million (26% of net sales) in 2019 compared to $392.3 million (26% of net sales) in 2018. Sales and marketing expenses were primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses, and other promotional expense. Higher costs in 2019 related to an increase in sales personnel, which was partially offset by lower share-based compensation and reduced third-party marketing activities. We anticipate that absolute sales and marketing costs will increase along with new product introductions and growth in sales of our products, but decrease as a percentage of sales.

General and Administrative

General and administrative expenses increased by 7% to $112.3 million (7% of net sales) in 2019 from $104.6 million (7% of net sales) in 2018. The increase in general and administrative expenses in 2019 was primarily due to higher licensing costs in connection with continued investments in information technology systems, including cyber security, across the organization as well as an increase in the number of administrative personnel and higher share-based compensation expenses.

Acquisition-Related Intangible Amortization

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

During 2019, amortization expense on acquisition-related intangibles within operating expense decreased to $30.0 million, compared to $39.0 million in 2018. The decrease follows the full amortization of assets previously acquired in 2007. We expect acquisition-related intangible amortization will increase as a result of our future acquisitions.

Restructuring, Acquisition, Integration and Other, net

Restructuring, acquisition, integration and other, net was expense of $199.8 million in 2019 as compared to $28.7 million in 2018. During 2019, $163.0 million of charges are included in the 2019 Restructuring program as further discussed in Note 6 "Restructuring and Impairments". We expect to incur additional restructuring cost in 2020 as disclosed therein. In addition, during 2019, we continued to incur acquisition and integration costs related to the acquisitions discussed in Note 5 "Acquisitions and Divestitures". In addition, a $7.4 million gain from the reduction

in the fair value of contingent consideration was recognized during 2019 discussed in Note 15 "Financial Instruments and Fair Value Measurements". Further, as we further integrate acquired companies and pursue opportunities to gain efficiencies, we expect to continue to incur additional business integration costs in 2019.

Long-lived Asset Impairments

Impairments to intangible assets and property, plant and equipment in 2019 totaled $140.0 million, of which $138.8 million was incurred in connection with the 2019 restructuring measures as further discussed in Note 6 "Restructuring and Impairments". During 2018, impairments to property, plant and equipment included $1.6 million related to the 2017 Restructuring program also discussed in Note 6 and $6.3 million related to strategic shifts in our business.

Other Income (Expense)

Total other expense, net was $51.6 million in 2019, compared to $40.8 million in 2018. Total other expense, net is primarily the result of interest expense, partially offset by interest income and other income (expense), net.

For the year ended December 31, 2019, interest income increased to $22.1 million from $20.9 million in 2018. Interest income includes interest earned on cash, cash equivalents and short-term investments, income related to certain interest rate derivatives as discussed in Note 14 "Derivatives and Hedging" in the accompanying consolidated financial statements and other components including the interest portion of operating lease transactions. Interest income earned in 2019 includes interest on higher cash balances following the issuance of cash convertible notes in November 2018.

Interest expense increased to $74.2 million in 2019, compared to $67.3 million in 2018. Interest costs primarily relate to debt, discussed in Note 16 "Lines of Credit and Debt" in the accompanying consolidated financial statements and the increase in interest expense reflects the issuance of cash convertible notes in November 2018 which bear interest at a higher rate than the notes that matured in 2019.

Other income (expense), net was $0.4 million of income for the year ended December 31, 2019. Other income includes $7.8 million of upward adjustments resulting from observable price changes for non-marketable investments not accounted for under the equity method, $2.1 million in income from equity-method investments and a $0.7 million gain from receipt of shares in settlement of a zero-book value financial instrument held with a third party, all as discussed further in Note 10 "Investments". This income was partially offset by impairments, including $4.8 million of impairments in non-marketable investments accounted for under the equity method as discussed further in Note 10 "Investments", and net losses on foreign currency of $5.7 million for the year ended December 31, 2019.

Other income (expense), net was $5.6 million of income for the year ended December 31, 2018. Other income includes $13.1 million of upward adjustments resulting from observable price changes for non-marketable investments not accounted for under the equity method, a $5.1 million gain from the sale of our interest in a non-publicly traded company and $2.6 million in income from equity-method investments, all as discussed further in Note 10 "Investments". Additionally in 2018, we recorded a divestiture gain of $8.0 million as discussed in Note 5 "Acquisitions and Divestitures". This income was partially offset by impairments, including $6.1 million of impairments in non-marketable investments accounted for under the equity method as discussed further in Note 10, and net losses on foreign currency of $12.3 million for the year ended December 31, 2019.

Provision for Income Taxes

Our effective tax rates differ from The Netherlands statutory tax rate of 25% due in part to our operating subsidiaries being exposed to tax rates ranging from zero to 35%. In 2019 and 2018, our effective tax rates were 46.7% and 15.7%, respectively. The comparison is impacted by pre-tax book income which was lower in 2019 at a pre-tax book loss of $77.8 million compared to pre-tax book income of $225.7 million in 2018. Fluctuations in the distribution of pre-tax (loss) income among our operating subsidiaries can lead to fluctuations of the effective tax rate in the consolidated financial statements. In 2019 and 2018, tax expense on foreign operations was favorably impacted by lower income tax rates and partial tax exemptions on foreign income primarily derived from operations in Germany, Singapore, Switzerland, Ireland, Dubai and Luxembourg. These foreign tax benefits are due to a combination of favorable tax laws, regulations, rulings, and exemptions in these jurisdictions. In particular, intercompany foreign royalty income in Germany is statutorily exempt from trade tax. Further, we have intercompany financing arrangements through Luxembourg, Dubai and Ireland in which the intercompany income is partially exempt.

See Note 17 "Income Taxes" to the consolidated financial statements for a full reconciliation of the effective tax rate to The Netherlands statutory rate.

In future periods, our effective tax rate may fluctuate from similar or other factors as discussed in “Changes in tax laws or their application could adversely affect our results of operations or financial flexibility” in the “Risks” section above.

Foreign Currencies

QIAGEN N.V.’s reporting currency is the U.S. dollar, and most of our subsidiaries’ functional currencies are the local currencies of the countries in which they are headquartered. All amounts in the financial statements of entities whose functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows: (1) assets and liabilities at period-end rates, (2) income statement accounts at average exchange rates for the period, and (3) components of shareholders’ equity at historical rates. Translation gains or losses are recorded in shareholders’ equity, and transaction gains and losses are reflected in net income. The net loss on foreign currency transactions is included in other income (expense), net, and in 2019, 2018 and 2017 was $5.7 million, $12.3 million, and $3.3 million, respectively.

Derivatives and Hedging

In the ordinary course of business, we use derivative instruments, including swaps, forwards and/or options, to manage potential losses from foreign currency exposures and variable rate debt. The principal objective of such derivative instruments is to minimize the risks and/or costs associated with global financial and operating activities. We do not utilize derivative or other financial instruments for trading or speculative purposes. We recognize all derivatives as either assets or liabilities on the balance sheet, measure those instruments at fair value and recognize the change in fair value in earnings in the period of change, unless the derivative qualifies as an effective hedge that offsets certain exposures. In determining fair value, we consider both the counterparty credit risk and our own creditworthiness, to the extent that the derivatives are not covered by collateral agreements with the respective counterparties. To determine our own credit risk, we estimated our own credit rating by benchmarking the price of our outstanding debt to publicly-available comparable data from rated companies. Using the estimated rating, we quantify our credit risk by reference to publicly-traded debt with a corresponding rating.

Foreign Currency Derivatives

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

Interest Rate Derivatives

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

We also make use of economic hedges. Further details of our derivative and hedging activities can be found in Note 14 "Derivatives and Hedging" to the accompanying consolidated financial statements.

Liquidity and Capital Resources

To date, we have funded our business primarily through internally generated funds, debt, and private and public sales of equity. Our primary use of cash has been to support continuing operations and our investing activities including capital expenditure requirements and acquisitions. As of December 31, 2019 and 2018, we had cash and cash equivalents of $623.6 million and $1.16 billion, respectively. We also had restricted cash of $5.7 million and short-term investments of $129.6 million at December 31, 2019. Cash and cash equivalents are primarily held in U.S. dollars and euros, other than those cash balances maintained in the local currency of subsidiaries to meet local working capital needs. At December 31, 2019, cash, cash equivalents and restricted cash had decreased by $529.7 million from December 31, 2018, primarily as a result of cash used financing activities of $639.1 million and cash used in investing activities of $222.3 million, partially offset by cash provided by operating activities of $330.8 million. As of December 31, 2019 and 2018, we had working capital of $618.9 million and $1.18 billion, respectively.

Operating Activities

For the years ended December 31, 2019 and 2018, we generated net cash from operating activities of $330.8 million and $359.5 million, respectively. While the net loss was $41.5 million in 2019, non-cash components in income included $231.5 million of depreciation and amortization and $144.8 million non-cash impairments primarily recorded in connection with the restructuring discussed in Note 6 "Restructuring and Impairments", $40.8 million of amortization of debt discount and issuance costs and $65.9 million of share-based compensation expense. Operating cash flows include a net decrease in working capital of $28.6 million excluding changes in fair value of derivative instruments. The current period change in working capital is primarily due to increased inventories and accounts receivable and decreased accrued and other current liabilities. Because we rely heavily on cash generated from operating activities to fund our business, a decrease in demand for our products, longer collection cycles or significant technological advances of competitors would have a negative impact on our liquidity.

Investing Activities

Approximately $222.3 million of cash was used in investing activities during 2019, compared to $211.4 million during 2018. Investing activities during 2019 consisted principally of $294.0 million for purchases of short-term investments, $68.1 million in cash paid for acquisitions, net of cash acquired as discussed in Note 5 "Acquisitions and Divestitures", $118.0 million in cash paid for purchases of property and equipment, as well as $156.9 million paid for intangible assets and $5.2 million paid for strategic investments in privately and publicly held companies as discussed in Note 10 "Investments", partially offset by $396.1 million from the sale of short-term investments.

Investing activities during 2018 consisted principally of $172.8 million of cash paid for acquisitions, net of cash acquired, $568.0 million for purchases of short-term investments, partially offset by $691.8 million from the sale of short-term investments.

Financing Activities

For the year ended December 31, 2019, cash used in financing activities was $639.1 million compared to cash provided by financing activities of $360.4 million in 2018. Financing activities during 2019 consisted primarily of $506.4 million repayments of long-term debt including $430.0 million for the amount due for the 2019 Cash Convertible Notes, $73.0 million for amounts due for the U.S. Private Placement and $3.4 million for a portion of the 2021 Cash Convertible Notes which was converted during the contingent conversion period as discussed further in Note 16 "Lines of Credit and Debt". In addition, repurchases of QIAGEN shares totaled $74.5 million during 2019.

In 2018, cash provided from financing activities totaled $360.4 million primarily due to $494.9 million net cash proceeds from the 2018 cash convertible offering. We used $97.3 million of the proceeds from the from the cash convertible offering to pay the premium for a call option related to the cash convertible notes, and simultaneously received $72.4 million from the sale of Warrants, for a net cash outlay of $24.9 million for the call spread overlay. Cash provided in 2018 was further offset by the repurchase of QIAGEN shares totaling $104.7 million.

Cash used in other financing activities during the year ended December 31, 2019 and 2018 consisted primarily of $10.5 million and $5.5 million paid for contingent consideration, respectively, together with $0.4 million cash received and $2.0 million cash paid in connection with derivative collateral arrangements, respectively.

Other Factors Affecting Liquidity and Capital Resources

In November 2018, we issued $500.0 million aggregate principal amount of Cash Convertible Senior Notes which is due in 2024 (2024 Notes). The net proceeds of the 2024 Notes were $470.0 million, after payment of the net cost of the Call Spread Overlay and transaction costs paid through December 31, 2019 as described more fully in Note 16 "Lines of Credit and Debt". Interest on the 2024 Notes is payable semiannually in arrears at a rate of 1.000% per annum. The 2024 Notes will mature on November 13, 2024 unless repurchased or converted in accordance with their terms prior to such date.

In September 2017, we issued $400.0 million aggregate principal amount of Cash Convertible Senior Notes which are due in 2023 (2023 Notes), which are discussed fully in Note 16 "Lines of Credit and Debt". Interest on the 2023 Notes is payable semiannually in arrears at a rate of 0.500% per annum. The 2023 Notes will mature on September 13, 2023 unless repurchased or converted in accordance with their terms prior to such date.

Additionally in 2017, we completed a German private placement of $329.9 million, net of issuance costs, consisting of several tranches denominated in either U.S. dollars or Euro at either floating or fixed rates and due at various dates through June 2027 as described in Note 16 "Lines of Credit and Debt".

In October 2016, we extended the maturity of our €400 million syndicated revolving credit facility, which now has a contractual lifetime until December 2021 of which no amounts were utilized at December 31, 2019. The facility can be utilized in Euro, British pounds sterling, Swiss franc or U.S. dollar and bears interest of 0.40% to 1.20% above three months EURIBOR, or LIBOR in relation to any loan not in euro, and is offered with interest periods of one, two, three or six months. We have additional credit lines totaling €26.6 million with no expiration date, none of which were utilized as of December 31, 2019.

In March 2014, we issued $730.0 million aggregate principal amount of Cash Convertible Senior Notes of which $433.4 million was paid in 2019 and $296.6 million is due in 2021 (2021 Notes). Interest on the 2021 Notes is payable semiannually in arrears on September 19 of each year, at rate of 0.875% per annum. The 2021 Notes will mature on March 19, 2021, unless repurchased or converted in accordance with their terms prior to such date.

In October 2012, we completed a U.S. private placement through the issuance of new senior unsecured notes at a total amount of $400 million with a weighted average interest rate of 3.66% (settled on October 16, 2012). The notes were issued in three series: (1) $73 million 7-year term due and paid in 2019 (3.19%); (2) $300 million 10-year term due in 2022 (3.75%); and (3) $27 million 12-year term due in 2024 (3.90%).

As of December 31, 2019, we carry $1.7 billion of long-term debt, of which $285.2 million is current. We did not hold any material finance leases as of December 31, 2019.

In connection with certain acquisitions, we could be required to make additional contingent cash payments totaling up to $179.4 million based on the achievement of certain revenue and operating results milestones as further discussed in Note 20 "Commitments and Contingencies".

In January 2018, we announced our fifth share repurchase program of up to $200 million of our common shares. During 2019, we repurchased 2.0 million QIAGEN shares for $74.5 million (including transaction costs) bringing the total shares repurchased under this program to 4.9 million for $179.1 million (including transaction costs). Repurchased shares will be held in treasury in order to satisfy various obligations, which include employee share-based remuneration plans. Repurchased shares will be held in treasury in order to satisfy various obligations, which include employee share-based remuneration plans.

In January 2017, we completed a synthetic share repurchase that combined a direct capital repayment with a consolidation of shares. The transaction was announced in August 2016 and involved an approach used by various large, multinational Dutch companies to provide returns to shareholders in a faster and more efficient manner than traditional open-market purchases. $243.9 million was repaid to shareholders through the transaction and the outstanding number of common shares was reduced by 8.9 million, or 3.7%. As discussed further in Note 18 "Equity", the capital repayment program was completed in January 2017.

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

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

Off-Balance Sheet Arrangements

Other than our former arrangements with QIAGEN Finance as discussed in Note 16 "Lines of Credit and Debt" to the consolidated financial statements, we did not use special purpose entities and do not have off-balance sheet financing arrangements as of and during the years ended December 31, 2019, 2018 and 2017.

Contractual Obligations

As of December 31, 2019, our future contractual cash obligations are as follows:

	Payments Due by Period						
Contractual Obligations (in thousands)	Total	2020	2021	2022	2023	2024	Thereafter
Long-term debt[1]	$1,790,350	$25,438	$347,230	$491,356	$356,738	$552,636	$16,952
Purchase obligations	194,596	126,121	35,915	26,337	3,223	3,000	—
Operating leases	61,520	19,914	16,009	11,885	7,119	3,391	3,202
License and royalty payments[2]	37,455	11,434	9,012	6,507	4,382	1,823	4,297
Total contractual cash obligations	$2,083,921	$182,907	$408,166	$536,085	$371,462	$560,850	$24,451

[1] Amounts include required principal, stated at the current carrying values, and interest payments. Future 2020 contractual cash obligations include only amounts due in cash. The 2021 Notes that became convertible pursuant to the indenture on January 1, 2020 as further discussed in Note 16 "Lines of Credit and Debt" and are classified as current as of December 31, 2019, are only convertible during the triggered conversion period and are thus not included as a cash payment until the 2021 date in the table above.

[2] As of December 31, 2019, $10.0 million and $14.5 million are included in accrued and other current liabilities and other long-term liabilities, respectively, associated to future license payments.

In addition to the above, and pursuant to the purchase agreements for certain acquisitions and other contractual arrangements, we could be required to make additional contingent cash payments totaling up to $179.4 million based on the achievement of certain revenue and operating results milestones as follows:

(in thousands)	Contingent Cash Payments
2020	$ 152,750
2021	11,800
2022	5,900
2024	5,900
Anytime 12-month period from now until 2028	300
	$ 179,350

Of the $179.4 million total contingent obligation, we have assessed the fair value at December 31, 2019 to be $162.2 million, of which $142.6 million is included in accrued and other current liabilities and $19.6 million is included in other long-term liabilities in the accompanying consolidated balance sheet.

Liabilities associated with uncertain tax positions, including interest and penalties, are currently estimated at $60.6 million as of December 31, 2019 and are not included in the table above, as we cannot reasonably estimate when, if ever, an amount would be paid to a government agency. Ultimate settlement of these liabilities is dependent on factors outside of our control, such as examinations by each agency and expiration of statutes of limitation for assessment of additional taxes.

Dividend

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

Credit Rating

QIAGEN is currently not rated by any credit rating agency.

Management Report

Human Resources

Overview

The skills, knowledge, dedication and passion of our employees are critical for the success of QIAGEN. We want to recruit, support and retain the best employees, offering performance-based remuneration, development opportunities and measures to balance work and family life. We are committed to diversity in our teams, fueling innovation and engagement with our customers and business partners. In a fast-changing, competitive business environment, QIAGEN has a significant commitment to being an employer of choice and further enhancing our position as a great place to work. At the end of 2019, QIAGEN had 5,096 full-time equivalent employees, an increase of 3% from 4,952 at the end of 2018. Total personnel expenses including share-based compensation in 2019 were $484.7 million compared to $483.6 million in 2018.

Code of Ethics

QIAGEN has in place a Code of Conduct which qualifies as a code of ethics, as required by SEC and the New York Stock Exchange (NYSE) Listed Company Manual. The Code of Conduct applies to all of QIAGEN's employees, including our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. The full text of the Code of Conduct is available on our website at www.QIAGEN.com.

Training and Retention

At QIAGEN, we recognize that employees are our most important resource. Their exceptional talent, skill, and passion are key to our long-term success and corporate value. Employee development is therefore viewed as an integral success factor in creating lasting value for our customers, patients, colleagues, partners, and shareholders.

QIAGEN maintains a transparent framework, the QIAGEN Profile Navigator (QPN), to make career paths, job requirements and performance expectations clear based on objective criteria for all positions across our growing global organization. Our global Performance Enhancement System (PES) provides all employees and their managers with regular, one-on-one review sessions to discuss career development topics. PES sessions include discussion of an employee's goals and achievements, training needs and interests, career planning drawing upon the QPN role profile system, organizational development, and results of regular "180° surveys." Professional training and development are an ongoing process for all employees, tailored to different career paths. An employee's pursuit of training cycles from PES session to training participation, review, follow-up, and back to PES review. QIAGEN's compensation structure (see below) ties in with the QPN role profiles and PES performance evaluations.

Management & Leadership Campus (MC & LC)

This program, composed of two components, is designed to ensure the ongoing development of QIAGEN's future management generations. Management Campus prepares high-performing employees to take an initial leadership position. The program provides management basics and an overview of relevant business management topics. Leadership Campus accelerates the careers of our professionals by providing further insights into advanced leadership and management topics while focusing on individual development and business-related innovative actions. It is a senior executive program that is designed to increase the leadership skills and management knowledge of outstanding QIAGEN senior managers by a more individual development approach. The program mainly focuses on change management and leadership coaching sessions, as well as on business-related innovative actions.

Tuition Reimbursement / External Professional Programs

To support our future growth, QIAGEN managers are encouraged to support external training programs and courses that their employees need to attend in order to prepare for new tasks or an expanded role. Employees can apply for tuition reimbursement before they join an external program if the QIAGEN Academy does not offer a suitable internal course option. Courses range from Business Administration for scientists to tailored training options for specialists.

QIAGEN Academy

To support all QIAGEN employees in individual development, QIAGEN has an online learning management system (LMS), the QIAGEN Academy. It manages the entire training process from enrollment to certificate conveniently in one platform. The QIAGEN Academy is available to every employee 24/7 via the internet. Continual and flexible access to all training materials at any time allows employees to blend different learning methods such as virtual classrooms, web-based training, videos or classroom training into holistic and sustainable learning concepts. We offer a huge training catalog with a wide range of development options aligned to QIAGEN's competency model. The training catalog is frequently reviewed with the commercial training team to align with trainings offered in the areas of sales and products.

For more information about our training system, please also refer to the section "Employee matters" in our non-financial statement included in this report.

Compensation System

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

It is critical for QIAGEN to offer attractive compensation packages on a global basis. According to the QIAGEN philosophy, an employee who achieves his or her performance objectives should generally be awarded compensation comparable to the median levels of compensation provided by relevant benchmark companies. QIAGEN participates in various compensation benchmarking surveys that provide information on the level and mix of compensation awarded by various companies and industries for a broad range of positions around the world. In the case of QIAGEN, these include many peer life science and diagnostics companies based in the U.S.

QIAGEN has a "pay for performance" culture, with the compensation of employees linked to the achievement of corporate financial and individual performance goals. Business goals are established by senior management. These goals are set at ambitious levels each year to motivate and drive performance, with a focus on both short-term and long-term quantifiable objectives. Performance metrics used for these goals include the achievement of targets for net sales, adjusted operating income and free cash flow. In 2019, the payments for short-term variable compensation were based on 90% achievement of the business goals. Compensation for a significant majority of employees worldwide includes fixed base compensation and benefits, which vary according to local market customs, as well as a short-term variable cash bonus. The level of fixed compensation is paid in cash, usually on a monthly basis, and is designed to provide the employee with a reasonable standard of living relative to the compensation offered by peer companies. The amount of short-term variable cash bonus is designed to reward performance, with the payout amount based on the achievement of overall corporate financial results as well as individual performance against a written set of objectives.

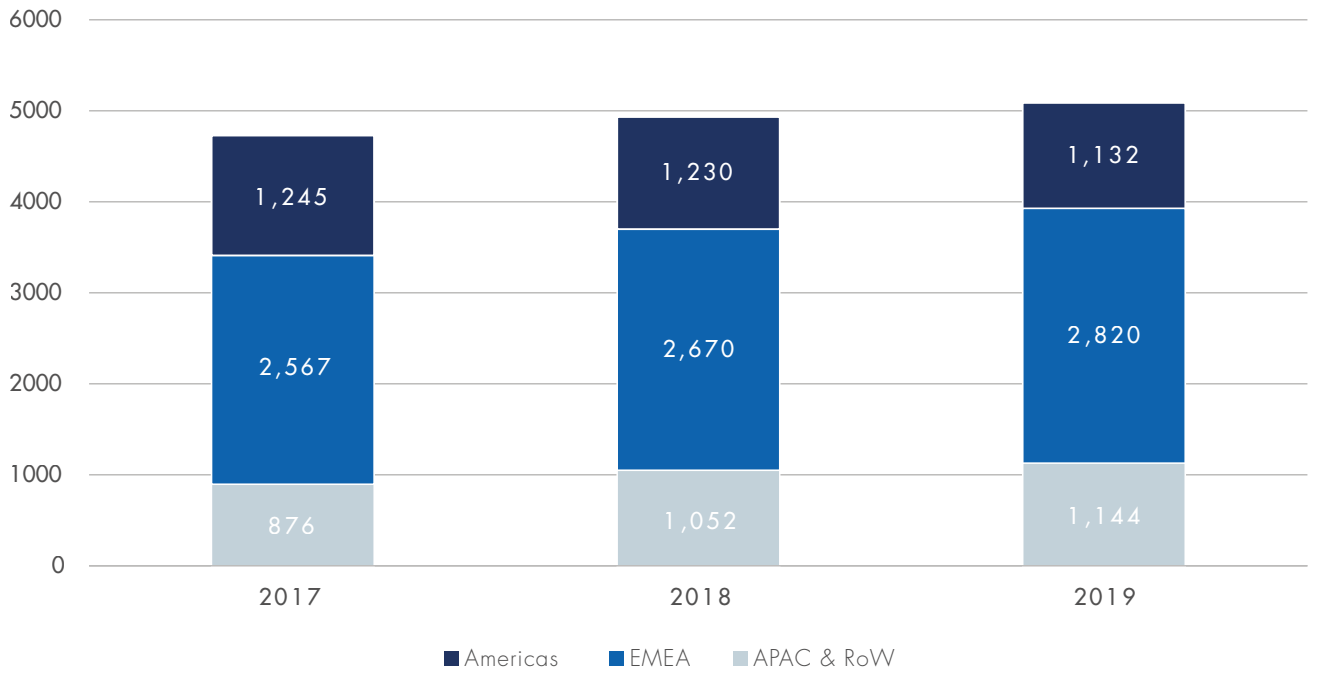
For the Interim Chief Executive Officer, the target annual short-term variable cash bonus is set at 100% of the annual base salary and the maximum is equivalent to 175% of the annual base salary. The Chief Financial Officer has a target annual short-term variable cash bonus set at 48% with the maximum being equivalent to 74% of the annual fixed salary. Furthermore, to align our compensation programs with the interests of shareholders, senior executives receive a portion of their total compensation in the form of long-term compensation, which is granted as equity as a reward for performance. These grants are determined on an individual basis and approved by the Compensation Committee. These equity grants are made in the form of Performance Stock Units (PSUs) with a staggered vesting period typically over three (40%) and five years (60%) .

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

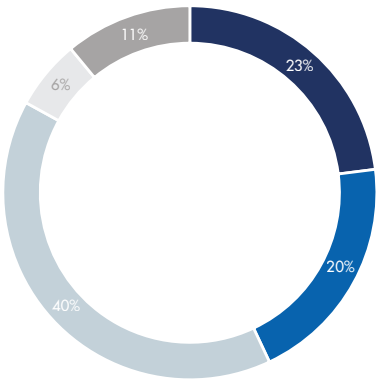
Workplace Health

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

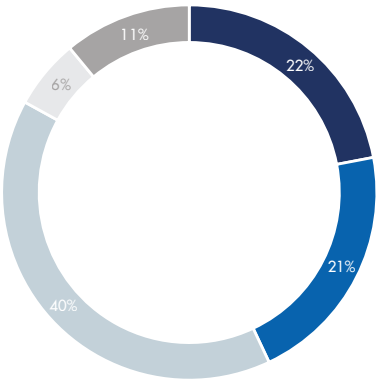
Employees worldwide



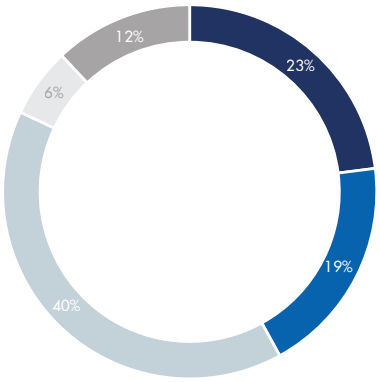
2017



2018



2019



Production
R&D
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Marketing
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Management Report

Non-Financial Statement

Our Approach to Sustainability

For QIAGEN, sustainability means long-term economic success combined with respect for the natural environment and healthy, high-performance workplaces, with the aim to make improvements in life possible as a good corporate citizen.

Our commitment to sustainability goes beyond formal regulations. As a market and innovation leader in life sciences and molecular diagnostics, we believe there is room for innovation in driving sustainable development in our industry, and we are resolved to continue moving forward.

In order to continuously address, monitor, and manage sustainability topics, QIAGEN has implemented a global function within our operations structure in 2019. This function will head QIAGEN's global environmental, health and security topics. This position has responsibility and oversight for sustainability at QIAGEN and reports to the Head of Global Operations, which is part of QIAGEN's Executive Board.

We pledge to continually evaluate the potential environmental impact of our business, saving energy and reducing negative environmental impacts of our operations. We look after the welfare of our employees, taking care of their developmental needs and supporting them in every way to become and remain committed and responsible. We extend our commitment to sustainability into the supply chain, committing our business partners to sign up to our environmental, social and human-rights related standards.

We recognize that ongoing success for QIAGEN also depends on the sustainability of society's resources. This is why we engage in dialogue with our various stakeholders – employees, customers, patients, suppliers, shareholders, non-governmental organizations (NGOs) and communities – to gain a better understanding of our operating environment, including market developments and cultural dynamics through approaches ranging from standard questionnaires to one-on-one conversations. Our employee-led volunteer sustainability committees drive progress by identifying areas for environmental improvement at all levels of the company, initiating projects, and providing input on environmental topics.

Please find information about our business model, organizational structure, products, customers, business strategy, as well as main trends and issues pertaining to the reporting year, in our Management Report.

Material non-financial information

For guidance on materiality and non-financial disclosure, we base our non-financial reporting on the Sustainability Reporting Standards (SRS) of the Global Reporting Initiative (GRI) Standards 2016 as well as on relevant sustainability accounting standards as issued by the Sustainability Accounting Standards Board (SASB).

In the reporting period, we reviewed the materiality analysis first conducted in 2017. As a first step, a long list of potentially relevant topics was drawn up, based on relevant sustainability frameworks, rating requirements and a competitive analysis. The five non-financial aspects prescribed in the European Commission's CSR Directive 2014/95/EU (environmental, social and employee matters, respect for human rights, anti-corruption and bribery) were also taken into account. In a second step, the topics were consolidated into a list of 17 topics and evaluated in an online survey of QIAGEN representatives with regard to their business relevance and their impact on the non-financial aspects. In a joint workshop with representatives from our different departments, the results of the survey were discussed and the various perspectives assessed. The final materiality matrix was validated by our senior management and resulted in the following material topics:

- Environmental matters: energy and emissions, water consumption, resource efficiency, sustainable procurement
- Employee matters: employee satisfaction, occupational safety and health protection, employee development, responsible employer, equal opportunities
- Social matters: access to healthcare, quality and product safety, customer satisfaction, data and cyber security
- Respect for human rights: conflict minerals
- Anti-corruption and bribery matters: antitrust, anti-corruption

Environment

At QIAGEN, we aim to save energy and reduce the environmental impact of our operations by driving long-term economic success with healthy, high performance workplaces and make improvements in life possible as a good corporate citizen. Reducing our environmental impact is a key corporate goal for 2020 and beyond that all employees are actively engaged in working towards.

As an international pioneer in our industry when it comes to eliminating harmful substances and waste products in laboratories, we have seen the value of environmentally responsible solutions as a source of competitive advantage, as well as an act of corporate citizenship.

To support this commitment a new Global Environment, Health and Safety (EHS) function was initiated in 2019 to drive the implementation of international environmental management systems in our production and research and development facilitates, to set goals and objectives to set limits to reduce the consumption of energy and water and to reduce the amount of plastic used in our packaging, during transportation. With these efforts, we aim to operate in the most cost-efficient and environmentally friendly way possible.

QIAGEN recognizes risks resulting from climate change such as extreme weather events, changes in regulation or customer behavior. Operations could for example be negatively impacted by volatility in the cost of raw materials, components, freight and energy. New laws or regulations adopted in response to climate change could increase energy costs, the costs of certain raw materials, components, packaging and transportation.

To proactively minimize our contribution to climate change, QIAGEN has committed to reducing emissions in line with a 1.5 degree Celsius climate target. Our 2019 carbon footprint, which was calculated with market-based emissions factors, will serve as the base year. By the year 2022, QIAGEN will reduce scope 1 and 2 emissions by 12.6% and business travel emissions by 3.7% below the base year. QIAGEN will achieve these reductions by establishing an energy efficiency task force that will identify areas for energy efficiency across the company and through purchasing green energy attributed certificates and high-quality carbon credits.

Environmental Performance

To increase transparency regarding our own global energy consumption and greenhouse gas emissions, QIAGEN has extended the coverage of the energy consumption data by the integration of a centralized data collection process management for all production sites, research centers and major offices.

The expansion in the collection of our energy data enabled us to calculate our corporate carbon footprint (CCF) for scope 1, 2 and 3 emissions more accurately in the reporting year and report it following a location-based and market-based approach for our scope 2 emissions. Scope 1 covers direct greenhouse gas emissions (GHG emissions) from combustion of fossil fuels on our own premises; scope 2 are indirect emissions originating from external generation of electricity for our operations. A location-based calculation method for scope 2 emissions reflects the average emissions intensity of grids on which energy consumption occurs; a market-based method reflects emissions calculated with the particular energy source mix used by each QIAGEN site.

As of 2018, all relevant scope 1 and 2 emissions are included following a location-based approach. The additional calculation using a market-based approach for scope 2 emissions was introduced for 2019 as part of our climate strategy. Accordingly, we will report our KPIs for GHG emissions using the market-based approach from next reporting year on. In addition, we have started to collect data for calculating GHG emissions in scope 3. These emissions occur along our value chain, for example through transport services, suppliers or the use of our products. As a first Scope 3 category, we have integrated emissions resulting from business travel into our CCF for 2019.

In addition to our energy and climate management activities, we collect data regarding fresh water consumption and waste for all our production sites. The table below lists figures from 2019 and 2018, and expresses our consolidated environmental data in relation to our production volume sold to establish a basis for a long-term monitoring system.

	2019[1]	KPI 2019		2018	KPI 2018	
Energy (in MWh)	86,158	0.0188	MWh/unit	86,549[2]	0.0248	MWh/unit
GHG emissions Scope 1 + 2 (in tCO_2; location-based)	29,347	6,429	g/unit	28,898[2]	8,294	g/unit
Freshwater use (in m^3)	474,335	104	l/unit	119,621	34	l/unit
Total waste (in t)	1,155	253	g/unit	633	182	g/unit
Hazardous waste (in t)	330	72.3	g/unit	250	71.7	g/unit

(1) Extension of the scope in 2019: All sites reported energy and emissions data. 25 sites reported water consumption data.
(2) Figures for 2018 were adjusted due to improved data availability.

Our global data collection coverage of energy and emissions was increased from 30% in 2017 to 100 % in 2019. In 2019, we achieved a decrease of 0.3 GWh in our total energy consumption to 86.2 GWh compared to 86.5 GWh in 2018 as detailed in the table below.

Energy consumption by source (in kWh)	2019	2018
Natural gas	34,679,620	38,627,496
Petrol	8,677,185	7,910,565
Diesel	5,255,293	8,160,611
Liquefied Petroleum Gas (LPG)	50,179	72,702
Electricity procurement from conventional tariffs	36,130,248	30,346,347
Electricity procurement from green tariffs	1,142,240	1,238,345
Consumption from district heating, district cooling and steam	223,000	193,000
Total energy consumption	86,157,765	86,549,066

	Footprint 2019	
Emission category (in tCO_2)	Location-based	Market-based
Scope 1: Direct emissions	10,808	10,808
Scope 2: Indirect emissions	18,540	10,870
Scope 3: Business travel	19,431	19,431

With the help of these key performance indicators (KPIs), we are able to create reduction targets for energy and CO_2-emissions. We are furthermore working towards creating targets for fresh water and waste.

Product life cycle assessment

QIAGEN conducted a life cycle assessment (LCA) for one of its best-selling – and therefore representative – products, the QIAamp DNA Mini Kit. The studied product is part of the portfolio category "consumables & bioinformatics", which about 90% of QIAGEN's sales (by turnover) are filed under. At about 2.5 kg, the kit is marginally heavier than an "average" QIAGEN kit.

The scope of the study has been the full life cycle of the product, including extraction and processing of raw materials, transport to the customer, energy and material input required when using the product, as well as transport to the disposal facility and incineration of remaining materials. These system boundary settings are called "cradle to grave". The assessment was carried out in accordance to ISO 14040/14044 but has not been certified by an independent third party.

The results of the LCA show that the largest relative impacts result from the production of plastic, transport and electricity during production and use. Furthermore, cardboard and paper production play a role, as well as the incineration of plastics and the evaporation of alcohol during use.

A very relevant issue is ecotoxicity impacts to marine aquatic systems due to the production of polypropylene as well as electricity generation. The depletion of fossil resources is rated second in relevance since plastics have multifold impacts being made from fossil resources and depleting a large amount of fossil resources for meeting the energy demand during their production. Transport and electricity generation both use large amounts of fossil resources for fuel as well. Global Warming Potential is rated third in relevance and similarly is closely linked to energy demand due to transport, plastics and electricity production. Plastics also have multi-fold impacts here, since their embodied carbon is released to the atmosphere during incineration. Different assumptions regarding disposal could significantly change the overall impacts of the product system, ranging from recycling (likely to have beneficial impact) to landfilling (likely to have adverse impact). Although open dumps and landfills are the most prevalent form of solid waste disposal globally, incineration at the end of life is deemed an accepted and reasonably conservative approach for this product.

Overview of impact results

Impact Category	Result	Unit	Processes	Share
Toxic effects on marine water systems (MAETP)	941	kg DCB eq.	Polypropylene	44%
			Electricity	43%
			Transport	9%
			Polyethylene	1%
			Rest	2%
Depletion of fossil resources (ADP fossil)	289,0	MJ	Polypropylene	44%
			Transport	31%
			Electricity	13%
			Polyethylene	4%
			Rest	8%
Global warming potential, excluding biogenic carbon (GWPe)	21,7	kg CO_2 eq.	Transport	30%
			Polypropylene	27%
			PP incineration	19%
			Electricity	16%
			Rest	8%
Photochemical creation of ozone ("summer smog") (POCP)	0,00638	kg Ethene eq.	Polypropylene	37%
			Alc. evaporation	30%
			Transport	23%
			Electricity	9%
			Rest	2%
Acidification of soil and water bodies (AP)	0,0549	kg SO_2 eq.	Polypropylene	43%
			Transport	35%
			Electricity	16%
			Polyethylene	2%
			Rest	4%
Toxic effect on humans (HTP inf)	0,643	kg DCB eq.	Electricity	34%
			Transport	23%
			Polyethylene	20%
			Polypropylene	7%
			Rest	15%
Depletion of abiotic resources, e.g. minerals (ADP elements)	1,69E-06	kg Sb eq.	Electricity	57%
			Rest	43%
Eutrophication (over-enrichment of nutrients in water bodies) (EP)	0,00744	kg Phosphate eq.	Transport	54%
			Rest	46%
Toxicity to freshwater ecosystems (FAETP)	0,0731	kg DCB eq.	Transport	41%
			Rest	59%
Depletion of ozone (i.e. the ozone layer) (ODP)	8,37E-11	kg R11 eq.	Paper	94%
			Rest	6%
Toxic effects on terrestric systems, i.e. soil (TETP)	0,00563	kg DCB eq.	Electricity	52%
			Rest	48%

* Relevance is calculated as the share of weights and normalized impact of the respective category.

The detailed report on the LCA results can be found on QIAGEN's website in the Sustainability section.

Plastic Footprint Reduction

The environmental impact of plastic materials is increasingly becoming a major concern for customers. QIAGEN currently uses plastics in many of its products and production support materials, as well as for transport and packaging purposes. This year, QIAGEN has set the goal of reducing Plastic Transportation Packaging Material by 3% vs 2019 for 2020. The reduction of plastic materials presents us and our industry with a number of challenges: Due to the use of our products in laboratory or medical applications, these products are subject to strict functional and legal requirements so in many cases other materials cannot simply be substituted for plastics. In the case of packaging materials, we must ensure that appropriate safety and hygiene standards are met.

In 2018, we set up a global cross-departmental Plastic Footprint Reduction focus team for "Plastic Footprint Reduction" to analyze the use of plastics and specifically identify reduction potential for QIAGEN. Our approach is to completely avoid unnecessary materials, develop more environmentally-friendly alternative materials, and where possible, optimize recyclability. Completed initiatives include reducing the thickness of blister film in packaging from 10 ml to 8 ml (reduction of 2.8 tonnes/year), reducing the number of gel packs used in cold shipment of our products (reduction of 33.4 tonnes/year), reducing the size of polystyrene foam boxes by optimizing how the contents are structured, and developing a digital recycling card that explains to customers how to properly dispose of packaging components.

To identify starting points within our supply chain, we have initiated a query with suppliers about their use of plastic materials. We are still in the process of exploring a "box cycle" where supplies are packaged directly by our suppliers and the packaging material is returned to them, with results expected in 2020. In addition, we are in discussions with suppliers in order to achieve a better recyclability of their products. Scrap plastics produced as part of the component production process are already recycled at major supplier sites.

Employees

QIAGEN's long-term success and growth are shaped decisively by the knowledge, skill and passion of our employees. Focusing on human capital therefore drives our economic performance and considerably influences the sustainability of our operations. We are convinced that the professional and personal development of our employees is an integral factor in creating value for our customers, patients, colleagues, partners and shareholders. Being the industry's employer of choice by attracting and developing top talent is one of our global goals. To achieve that, QIAGEN creates a work environment that empowers and involves employees at all levels.

As a company headquartered in the European Union, freedom of association and collective bargaining are cornerstones of the good relationship between management and representatives of employees. We don't have significant operations (more than 100 employees) in countries with severe legal limitations to freedom of association and collective bargaining. In all regions where we operate, we respect local laws and regulations concerning labor relations.

Among all QIAGEN guidelines, the following policies aim to incorporate QIAGEN's culture and values into all of our internal and external relationships. These are available internally for all employees.

Our Ethical Standards Policy: QIAGEN's cultural norms and values are defined in the "3I's: Identity, Inspire, Impact." Our values form the basis of our business success and every employee is expected to treat everyone in an open, honest, and respectful manner.

All our employees in the various regions of the world are covered by the relevant local laws or by our voluntary corporate guidelines to the greatest possible extent, which guarantee freedom of association and/or collective bargaining mechanisms.

Depending on local law and custom, there are different types of employment ranging from long-term fixed contracts to temporary positions, also including flexible time and programs for parents returning from childcare. In 2019, we employed 3.03% part-time employees (2018: 5.57%) and 1.24 % temporary employees with QIAGEN contract / fixed-term work contract (2018: 1.26%).

Employee training

As a fast-growing technology and knowledge-based company, we consider high-quality training and career development to be an integral part of our success. The QIAGEN Academy provides the possibility to either use our global e-learning portfolio or to participate in personal trainings usually offered in a blended format. The focus is on job-specific skills, competencies and leadership development.

In 2019, we ran a mix of internal instructor-led, virtual instructor-led and e-learning courses attended by 3,951 of 4,193 employees. 12% of these courses were attended by management level employees. In addition, 46 employees participated in our advanced leadership development programs.

As part of our talent and succession management, we have established transparent career paths with the QIAGEN Profile Navigator (QPN). It defines jobs, core competencies and approaches to advancement across the global organization.

In addition, QIAGEN's global Performance Enhancement System (PES) creates a clear framework of regular, one-on-one review sessions for each employee and their manager to discuss career development. These include discussions of goals and achievement levels, assessment of relevant competencies, as well as training needs and career planning steps.

The supervisor feedback process provides the opportunity for employees to provide anonymized feedback to their supervisors. For 2019, as in previous years, employees provided overall very positive feedback.

Diversity

Our Diversity & Inclusion Philosophy: At QIAGEN, we are committed to creating an environment rich in diversity. Diverse teams strengthen our organization through the variety of ideas of opinions. In addition, teams outperform and succeed when they are composed of individuals with the widest possible range of personalities, backgrounds and traits. Therefore, one of our goals is to maintain an environment where all individuals have the opportunity to grow and contribute to our progress.

We are committed to providing an environment where all individuals have the equal opportunity to grow and contribute to our progress; regardless of their age, educational background, sex (including gender identity and sexual orientation), nationality, veteran status, physical abilities, neurotype, race, ethnic background, or religion. Strategic consideration of diversity not only makes QIAGEN a better place to work. We also consider it to be a key success factor on the path to achieving our mission and goals.

As in 2018, the gender split across the whole company remained at 51% men and 49% women. The participation of women in leadership roles was at 29% (2018: 28%). We aim to achieve 30% women in leadership roles in 2020. Specific information about the diversity policy for the composition of the Managing Board and the Supervisory Board can be found in the Corporate Governance Report.

Employee satisfaction and retention

Recognizing that QIAGEN's employees are the key to our success, we seek to be a great place to work. QIAGEN offers opportunities to work on exciting tasks and projects in an engaging work environment. Employees join QIAGEN and stay with QIAGEN because they can see how their work makes a difference to people`s life everywhere in the world. Internal and external ratings have improved significantly and show QIAGEN's reputation and preferred position in the global working environment.

A prudent work-life balance is an important measure to create and maintain employee satisfaction. We provide services to help employees balance their personal lives with the company's dynamic work environment, including in-house childcare, sabbatical programs, and flexible working hours.

QIAGEN has implemented frameworks for performance-based compensation, equity-based compensation, and incentive programs for new ideas and innovation. These programs aim to ensure fair and attractive compensation and to encourage each employee to work for the company's long-term benefit.

An essential component of QIAGEN's efforts to maintain a high level of satisfaction at work is our corporate health and safety management. We offer a wide range of measures and tools, from annual "health days" with free counseling, screening and medical check-ups to sports opportunities in the form of in-house gyms, on-site soccer fields and beach volleyball courts.

QIAGEN's commitment to being an employer of choice is also reflected in the high number of applications for open positions, which exceeded 27,000 applications in 2019 (2018: > 40,000). At the same time, the average voluntary annual turnover rate has decreased year over year.

Occupational safety and health protection

QIAGEN recognizes its responsibilities with respect to health and occupational safety in all our operations and meets all applicable regulatory requirements. In the third quarter of 2019, a leading position for EHS (environment, health, safety) was appointed to provide direction and implementation of a global health and safety management system compliant with ISO45001, which will be implemented within the manufacturing facilities, research and development as well as business service centers over the next three years. All QIAGEN facilities operate health and safety procedures at local level, which include accident reporting, risk assessments and hazard analyses, and occupational safety and health audits, which lead to the implementation of improvement measures. All employees of the company are required to adhere to local health and safety procedures and practices. Safety, orderliness and cleanliness are demanded by management as a key success factor.

QIAGEN committed to an all company goal to reduce the number of lost days due to injuries by 10% vs 2019 over 2020, to drive and encourage initiatives to improve the safety culture in QIAGEN.

The table below table shows the total number of recordable incidents, (recordable accidents include lost workdays, restricted work, and medical treatment beyond first aid) and lost workdays for 2019, 2018 and 2017. The data is obtained from key QIAGEN manufacturing sites in Germany, US, China, Sweden and Tokyo. It also includes the research and development site in Manchester UK and the large business service center located in Poland. Thus data is equates to 60% of the total average number of employees. There were no reported fatalities for 2019 at any of the QIAGEN sites.

	Total Recordable Incidents			Days Lost due to Injuries		
	2019	2018	2017	2019	2018	2017
Europe / Middle East / Africa	17	28	21	121	261	52
Americas	3	26	23	5	16	18
Asia-Pacific / Japan	0	0	0	0	0	0

Human Rights

QIAGEN believes that the respect for human rights is an essential component of promoting sustainability in our global business. As a publicly listed company with international operations, we regard ourselves as a responsible corporate citizen in all the countries and regions where we do business. This role includes rights and obligations governed by international and national law, with human rights as one of the foundations of international law.

In this sense, we acknowledge and endorse the UN Universal Declaration of Human Rights, the European Convention on Human Rights, and the business-related Organisation for Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises, the ILO Declaration on Fundamental Principles and Rights at Work, and the UN Guiding Principles on Business and Human Rights and its application in National Actions Plans of our relevant jurisdictions.

In 2019, QIAGEN adopted a new Human Rights Policy, which is designed to provide guidance on all human rights issues in our sphere of influence such as in our relationship with customers, on the employee level, and in our supply chain. For more information on our due diligence processes with regard to human rights in our supply chain, please refer to the "Sustainable supply chain management" section.

Sustainable Supply Chain Management

QIAGEN strives to ensure that its quality standards, compliance with laws and regulations as well as environmental and social standards are maintained along the entire value chain of suppliers and partners. We demand the same from our business partners. Our procurement policy includes specific requirements for corporate governance, environmental and social standards, which we expect from our suppliers as minimum standards. Among other issues, it includes the obligations to reduce the use of substances of concern, to ensure collective bargaining and freedom of association among employees, fair wages, and regulations concerning maximum working time. The policy is publicly available on the QIAGEN Website.

In alignment with QIAGEN's Compliance Program (especially QIAGEN's Corporate Code of Conduct and Ethics), every QIAGEN employee must conduct themselves honestly, fairly, and objectively in all business relationships with suppliers and all others with whom QIAGEN maintains business relationships. Regular online training in the QIA-Academy ensures that employees in the procurement organization understand our guidelines and comply with them.

Structure of our supply chain

QIAGEN operates in over 35 locations worldwide. Our sites are supported by a global supplier network that includes approximately 9,000 suppliers in over 60 countries, supplying resources such as chemicals and bioreagents, plastics, packaging materials, as well as other materials and services essential to our business. In 2019, 83% of our overall purchasing volume came from OECD countries.

Region of origin of suppliers

Region of origin	%
Europe	53%
North America	24%
Asia	19%
Australia	3%
South America	1%
Africa	0%
Total	100%

Due diligence process

In order to minimize compliance, environmental and social risks in our supply chain, we apply a multi-stage vendor selection process. Suppliers are subjected to a risk analysis with regard to environmental and social criteria based on their geographic location. These criteria were supported by information from the MVO Nederlands platform financed by the Dutch Foreign Ministry as well as the Bertelsmann Stiftung's Sustainable Development Goals Index. As a result, 70 suppliers were identified for whom potential risks exist due to geographic location and sales to QIAGEN.

In 2019 all identified suppliers have signed QIAGEN's procurement policy. All new suppliers will need to sign the policy as part of the contracting process. The policy contains requirements with regard to legal compliance, bribery and corruption, labor rights, non-discrimination and fair treatment, health and safety as well as environmental protection and conservation. QIAGEN provides a whistleblower hotline which can be used by all employees. The contact details can be found on QIAGEN's website within the section Corporate Code of Conduct and Ethics.In addition, first-tier suppliers must confirm REACH, RoHS and SEC compliance as appropriate.

As part of our supplier selection process, we additionally assess the suppliers' policy with a perspective on QIAGEN's requirements. Supplier audits are conducted if non-compliance is suspected. Audits are conducted on-site, at least every three years for all "A"-categorized direct suppliers. Audits are documented and results are being shared with audited suppliers. To our knowledge, there were no violations regarding corporate governance, environmental and social standards in the reporting period.

Conflict minerals

The sourcing of certain minerals (known as "conflict minerals") has been linked with human rights abuses in the Democratic Republic of Congo ("DRC") and other conflict zones. QIAGEN has performed an extensive inquiry into the company's supply chain to confirm that the products supplied to us are either DRC conflict-free or that the suppliers are not aware of any non-compliance in their supply base. QIAGEN has no indication that any conflict minerals from the Democratic Republic of Congo or adjoining countries are used in the company's laboratory instruments.

Our products consist of sample and assay kits, known as consumables, and automated instrumentation systems. We do not believe that any conflict minerals are necessary to the production or functionality of any of our consumable products. We conduct due diligence measures annually to determine the presence of conflict minerals in our instrumentation products and the source of any such conflict Minerals. Because we do not purchase conflict minerals directly from smelters or refineries, we rely on our suppliers to specify to us their Conflict Minerals sources and declare their conflict minerals status. We disclosed our conflict minerals findings to the U.S. Securities and Exchange Commission ("SEC") for the calendar year ending December 31, 2019, on Form SD on March 27, 2020, and will provide updated disclosure to the SEC annually.

Data and Cyber Security

As the external threat landscape continues to evolve, managing cyber security risk is a priority for QIAGEN. The company continues to make investments in its capabilities to enhance cyber resilience of our organization, products, services and preserve the trust of our customers, partners and employees.

In 2019, QIAGEN further improved cyber security governance by establishing a dedicated cyber security function with global responsibilities and leadership. Building on our Information Security Framework, QIAGEN's cyber security program continues to ensure that security governance efforts and initiatives reflect evolving business requirements, regulatory guidance, and emerging threats. Our membership in private and public cyber security organizations (such as Health Information Sharing and Analysis Center, BSI Alliance for Cyber Security) facilitates close collaboration with peer organizations and government authorities to share industry-relevant best practices and threat information.

Business Ethics

For QIAGEN, conducting business in a responsible way includes looking beyond our day-to-day business operations into the ethical foundations of our company. This means, in particular, the respect for human rights and legally compliant business behavior.

Payments received from government

QIAGEN occasionally received grants for specified development activities from governments to support research and development activities. These grants are further discussed in section 3.7 Government Grants of Note 3 "Summary of Significant Accounting Policies, Estimates and Judgments" of the 2019 IFRS Annual Report.

Payments to governments

We pay income tax related to the value added by QIAGEN's operational activities to the governments in the global regions of operations as follows:

	Year ended December 31,		
($ in thousands)	2019	2018	2017
Europe / Middle East / Africa	$ 18,186	$ 14,120	$ 19,595
Americas	10,346	4,025	11,767
Asia-Pacific / Japan	12,942	11,172	9,137
Total income taxes paid, net	$ 41,474	$ 29,317	$ 40,499

Income taxes paid exclude government incentives due to favorable tax regulations in the U.S., Spain and the U.K. relating to research and development expense.

Financial assistance from governments

We conduct business globally and, as a result, file numerous consolidated and separate income tax returns in the Netherlands, Germany, and the U.S. federal jurisdiction, as well as in various other states and foreign jurisdictions.

Governments and public institutions do not hold any major shares in QIAGEN.

For additional information on the Group's income taxes please refer to Note 17 Income Tax.

Compliance

As a publicly listed company with international operations, QIAGEN is subject to regulation in various jurisdictions. Unethical behavior and non-compliance with laws and regulations have the potential to seriously harm our business, our reputation and our shareholders and to expose our employees to personal liability. QIAGEN has established a comprehensive Compliance Program, which translates legal and regulatory requirements as well as our fundamental values into clear, precise and understandable guidelines in our Corporate Code of Conduct and Ethics and supplementing specific policies for our employees. The policies include, but are not limited to, aspects as conflicts of interest, insider trading, revenue recognition, interactions with healthcare professionals, confidentiality and social media. QIAGEN does not make any payments to political parties or political action committees.

Special attention is paid to antitrust and anti-corruption laws (see http://financialreport.qiagen.com/management-report/opportunities-and-risks). Our specific antitrust and anti-corruption policies set forth our commitment to ensure that QIAGEN and its subsidiaries abide by the antitrust and anti-corruption laws of the countries in which we operate.

We extend our Compliance Program not only to our management and employees, but also to third-party intermediaries as distributors or agents. Third-party due diligence lies in the remit of the Sales Compliance Manager. This contains the following five elements:

1. Anti-corruption questionnaire and certification for new distributors, resellers and agents;
2. Annual risk assessment based on a calculated risk score, which factors location of business (Transparency International Index Score, TIIS) and annual sales revenue for distributing QIAGEN products by multiplying total revenues of the prior calendar year with the inverse of the TIIS;
3. Training;
4. Contractual obligations;
5. Due diligence (including selected background checks); also including payment monitoring.

All our policies are available to employees through the company's Compliance@QIAGEN intranet pages. Compliance awareness of our employees in all areas of the world is increased by regular trainings, which are held by external as well as inhouse legal and regulatory experts. In addition, QIAGEN has entered into a long-term online training program focusing on topics such as antitrust and competition, bribery and corruption, conflicts of interest, data protection, gifts and entertainment, harassment, insider trading, reporting as well as respectful communication. Online training reaches all employees in local language, supported by multiple communication resources. New employees are required to take online training on our Corporate Code of Conduct and Ethics at a minimum. Additional trainings which are customized to the specific area of responsibility are mandatory. Employees in Sales and Marketing as well as Upper Management are required to take training on anti-corruption and antitrust laws. These basic trainings are followed by refresher courses on a regular basis. In 2019, our employees completed more than 10,000 online training modules. In addition, employees are informed through the company's Compliance@QIAGEN intranet page and regular updates on compliance topics via the company's internal communication platform Yammer.

We have established a hotline for reporting accounting-related concerns on an anonymous basis in good faith. In accordance with the U.S. Sarbanes-Oxley Act of 2002 and the listing standards of NYSE, QIAGEN follows as strict non-retaliation policy. QIAGEN will diligently investigate all such complaints and will protect the anonymity of the complainant. We also offer a direct e-mail and telephone hotline for employees to address questions or make suggestions for our Compliance Program.

Our Compliance Program is overseen by the Compliance Committee under the leadership of the Head of Global Legal Affairs and Compliance, who reports in this function directly to the Audit Committee of the Supervisory Board. The Compliance Committee consists of managers from Legal, Internal Audit, Human Resources, Commercial Operations, Trade Compliance and Regulatory functions.

In the reporting period, QIAGEN had no legal actions pending or completed with regard to antitrust or corruption.

Social Matters

QIAGEN's mission is to make improvements in life possible by enabling our customers to achieve outstanding success and breakthroughs in life sciences, applied testing, pharma and molecular diagnostics. We are committed to customers and their patients to deliver innovative solutions that unlock new insights for scientific research, forensics, food safety or better treatment decisions. We understand and live up to our responsibility to customers and patients who depend on us for reliable, efficient and safe workflows.

Customer satisfaction

Customer satisfaction is an integral part of the QIAGEN mission of making improvements in life possible, which is therefore the direct responsibility of the Chief Executive Officer. Our customers have high expectations on reliability, safety and the environment-friendly manufacturing of our products. We develop our products and services in close contact with our customers and incorporate their feedback into our processes.

Our commitment is to continually improve the customer experience, taking into account their evolving needs and expectations. QIAGEN has established a global systematic approach to measure customer experience in the form of an aggregated Customer Experience Indicator (CEI). The CEI is measured on a monthly basis through a set of internal KPIs (product and delivery performance, phone support, etc.) and external customer feedback that are directly linked to customer experience in our transactions. Thus, we are able to identify quickly and systematically areas for improvement while staying closely connected with our customers. Departmental and employee contribution to the CEI performance is embedded into our annual goal setting process. After a reworking of the CEI logic and KPI definitions in 2018 and the launch of a revised CEI 2.0 in January 2019, a Full Year score of 96.331 points (out of a maximum 100 points) was achieved. This corresponds to 1,517 points with the former CEI logic (2018 score was 1,515 points out of 2,000 maximum). It is a testimony to our continued efforts to increase customer satisfaction.

Quality and product safety

QIAGEN stands for quality. Since QIAGEN's founding 30 years ago, we have always been committed to the highest quality, and we always strive to exceed our customers' expectations. QIAGEN's reputation as a quality supplier is best-in-class in our industry and the foundation of our loyal global customer base. Therefore, we offer a 100% satisfaction guarantee to all our customers. It means that if our customers are not entirely satisfied with the performance of a QIAGEN product we will exchange or refund it free of charge for the customer.

To achieve and maintain our quality standards, we established Total Quality Management (TQM) systems in all of our manufacturing facilities around the globe. These assure constant high quality as well as safe and effective medical devices. QIAGEN's TQM systems are certified according ISO 9001, ISO 13485, ISO 18385, as well as 21 CFR 820 and all other applicable medical device standards around the globe (see section "Government Regulations" in the Management Report).

QIAGEN products and their components are safe to use by customers as well by our employees in Research and Development (R&D). We use a list of qualified substances (the "MDx Toolbox"), specifically excluding any substances of concern. Our transparent and responsible product and development policy also includes the communication and marketing of products. As with all companies in the medical device/in vitro diagnostics industry, product claims and product properties are verified and validated during development and approved by regulatory bodies around the world as part of the product submission process.

QIAGEN, like other companies, is exposed to the financial implications of potential recalls and other adverse events due to equipment failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks. In the event of a recall, QIAGEN has established global procedures applicable to all QIAGEN sites that aim at avoiding the further use of the product and at guaranteeing cost-neutral procedures for our customers. Processes, responsibilities and improvement programs are defined as required by regulating authorities to avoid the reoccurrence of recalls. There is full traceability of each product to the final customer; therefore, any recalls are executed by direct customer notifications. Due to QIAGEN's stringent quality management, recalls rarely occur: 2019 (3), 2018 (4), 2017 (0), 2016 (3), 2015 (1). The percentage of affected product is low as well: 2019 (15%), 2018 (0.09%), 2017 (0%), 2016 (0.21%), 2015 (0.022%). In past recalls, 90% to 100% of customers have been reached and confirmed recall notification.

Access to healthcare

QIAGEN is aware of the importance of providing access to healthcare and research products around the world. In developing countries with scarce resources, new ways are needed to ensure access to affordable diagnostics that play a critical role in helping to prevent and treat diseases. In particular, infectious diseases and various malignancies can be treated much more cost-effectively through early and precise detection – and with improved patient outcomes. However, many emerging countries lack properly trained lab personnel and technical infrastructure to utilize the latest molecular testing technologies.

For QIAGEN, a strategic approach to providing access to diagnostic technologies can yield opportunities for growth, innovation and unique public-private partnerships. To support our growth strategy in emerging markets, we are expanding our presence in these markets and adapting our products to local needs, where necessary.

One example is our global effort to advance diagnostics for tuberculosis (TB) in low-resource, high disease burden countries. Based on a five-year memorandum of understanding signed in 2015, QIAGEN is cooperating with FIND, an NGO, to develop innovative and affordable tests to detect people with latent TB infections who are at risk of developing active TB. In October 2019, we also announced the addition of QuantiFERON TB Gold Plus (QFT-Plus) to the diagnostic catalogue of the Stop TB Partnership's Global Drug Facility (GDF). The GDF facilitates access and

helps match demand for TB diagnostics and drugs with funding from donors, governments and NGOs on a global scale. The acceptance of QFT-Plus to the GDF catalogue advances our strategy to help expand screening with modern blood-based assays for latent TB infection in regions with high disease burden but limited resources.

To reach the highest risk populations needing TB testing, QIAGEN is building upon our high-volume state-of-the-art QuantiFERON-TB Gold Plus assay with the development QuantiFERON-TB Access, a field-friendly test with ultrasensitive digital detection on a portable device. Launching in 2020, this public health solution has already gained recognition by the Joint United Nations Program on HIV/AIDS.

A further example is the development of careHPV as an adaptation of our gold standard digene HC2 test for detection of high-risk human papillomavirus (HPV), which has been shown to be the primary cause of cervical cancer. In cooperation with PATH, an NGO, and support from the Bill & Melinda Gates Foundation, QIAGEN developed this dedicated testing system for use in regions with limited healthcare resources. The main advantages of decentralized HPV testing are:

- immediate analysis at the point of care
- instant treatment decisions
- higher compliance of patients

Our careHPV Test is currently available in more than 25 countries worldwide. Since its launch through the end of 2019, more than 3 million tests have been distributed.

Management Report

Future Perspectives

QIAGEN Perspectives for 2020

The COVID-19 pandemic will have a significant impact on QIAGEN in 2020. Exatrordinary demand has emerged for molecular technologies involved in the testing for the new pathogen. However, the overall impact is not predictable at this point, as the spike in demand comes at the same time as demand for other products has waned due to the quarantines and other actions in many countries around the world that have disrupted the broader economy and routine healthcare.

Global Economic Perspectives for 2020

The world's economic perspectives for 2020 are impossible to predict at this time given the COVID-19 pandemic.

Industry Perspectives for 2020

Molecular testing solutions are seen as an essential component of the broad medical response to the COVID-19 pandemic. QIAGEN is committed to dramatically ramping up production capacity of its solutions that can be used for SARS-CoV-2 testing and support the overall response to this public health emergency.

Subsequent Events

On March 3, 2020, QIAGEN and Thermo Fisher Scientific Inc. (NYSE: TMO) announced that their boards of directors, as well as the managing board of QIAGEN N.V., unanimously approved Thermo Fisher's proposal to acquire QIAGEN for €39 per share in cash. The offer price represents a premium of approximately 23% to the closing price of QIAGEN's common stock on the Frankfurt Prime Standard on March 2, 2020, the last trading day prior to the announcement of the transaction. Thermo Fisher will commence a tender offer to acquire all of the ordinary shares of QIAGEN. The transaction values QIAGEN at approximately $11.5 billion at current exchange rates, which includes the assumption of approximately $1.4 billion of net debt. The transaction, which is expected to be completed in the first half of 2021, is subject to the satisfaction of customary closing conditions, including the receipt of applicable regulatory approvals, the adoption of certain resolutions relating to the transaction at an Extraordinary General Meeting of QIAGEN's shareholders, and completion of the tender offer. Thermo Fisher has obtained committed bridge financing. Permanent funding is expected to come from cash on hand and the issuance of new debt. The transaction is not subject to any financing condition.

In March 2020, the Supervisory Board and the Managing Board resolved in a Joint Meeting to propose Thierry Bernard, who has been with QIAGEN since 2015, for election as Chief Executive Officer and a Managing Director at the next Annual General Meeting, which is set to take place in June 2020, along with the re-election of Roland Sackers as Chief Financial Officer and a Managing Director. The Joint Meeting further resolved to propose the current members of the Supervisory Board to all stand for re-election: Håkan Björklund, Stéphane Bancel, Metin Colpan, Elaine Mardis, Lawrence Rosen and Elizabeth Tallett.