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. 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.

We 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, we have 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. Our industry-leading bioinformatics solutions allow users to analyze and interpret data with bioinformatics software and knowledge bases to provide relevant, actionable insights. Our automation systems can be used to tie these technologies together in seamless and cost-effective molecular testing workflows.

We have 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 our portfolio of molecular testing products in life science research and molecular diagnostics totals more than $11 billion. We continue to accelerate the growth of our portfolio of Sample to Insight solutions, delivering efficiency and effectiveness, increasing the value of QIAGEN as an employer of choice and enhancing the customer experience. Our growth strategy is anchored in our Five Pillars of Growth: sample technologies, the digital PCR platform QIAcuity, the clinical PCR automation solutions QIAstat-Dx and NeuMoDx and the QuantiFERON technology platform used to detect diseases such as latent tuberculosis.

We have funded our growth through internally generated funds, debt offerings, and private and public sales of equity securities. Our 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.

Operating Environment in 2020

Economic Environment

Global economic growth retracted by around 4% in 2020 as repeated waves of the SARS-CoV-2 virus triggered unprecedented shutdowns that pushed economic activity to record lows. Advanced economies including the United States, the euro area and Japan did not contract as much as initially feared and the Chinese economy recovered relatively quickly from the beginning of the year slump. These economies were saved from worse by strong and quick policy responses from governments – including fiscal stimulus, state aid for companies, and support payments for citizens – and central banks – including monetary easing, liquidity injections and targeted credit support. On the other hand, most emerging market or developing economies had to deal with more acute problems than initially expected. Nevertheless, the U.S. dollar ended a two-year period of steady strength as the COVID-19 crisis gripped the United States. At the end of 2020, the U.S. Dollar Index, which tracks the currency's value against other major currencies, was down 13% from its March highs and down 7% over the year.

Industry Environment

The molecular diagnostics market expanded during 2020 due to the significant demand for COVID-19 related testing solutions. The expanding use of polymerase chain reaction (PCR), antigen, antibody and T-cell testing significantly raised public awareness of molecular diagnostics and its potential. This unprecedented global attention is expected to fuel further acceptance of molecular diagnostics in the coming years, likely spurring its expanded usage.

Molecular testing stepped up to meet additional demands for insights in diagnostics, life science research, pharmaceutical R&D and public safety. Technologies for next-generation sequencing (NGS) and PCR continued to disseminate and evolve, making molecular testing more accessible, faster and more efficient. Molecular diagnostics is 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. 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.

In 2020, QIAGEN delivered 23% growth in net sales at constant exchange rates (CER) and 52% growth in adjusted earnings per share CER. QIAGEN experienced significant demand for solutions used in the COVID-19 pandemic and saw improving trends in other areas of the business during the second half of 2020. QIAGEN finished the year as an independent, stronger, and more focused company, ready to execute on growth in the years after the pandemic.

QIAGEN aligned its strategy on five pillars of growth to focus on its largest and most attractive growth opportunities. In 2020, it significantly raised its output of key consumables products such as sample technologies kits and QIAstat-Dx and NeuMoDx testing cartridges. It innovated in anticipation of changing testing demands and overcame market challenges as the pandemic evolved.

QIAGEN developed over ten new solutions for use in the pandemic – and beyond the COVID-19 crisis. Having made over 3,300 new placements last year, the company's installed base of instruments saw accelerated growth – and is now ready to serve both ongoing COVID and returning non-COVID applications. After the launch of the QIAcuity digital PCR platform in September 2020, QIAGEN delivered over 200 devices by year-end. By acquiring the remaining 80.1% stake in NeuMoDx in September 2020, QIAGEN secured the rights to commercialize its integrated PCR platforms in the U.S.

Our Products

Our leadership in molecular testing solutions leverages our product portfolio across a wide range of applications. We provide more than 500 core consumable products (sample and assay kits), instruments and automation systems, and bioinformatics solutions for analysis and interpretation. These products comprise two main categories: consumables and related revenues accounted for between 86% and 89% of total net sales during the last three years and includes sample and assay kits, bioinformatics solutions, royalties, co-development milestone payments and services while instruments includes related services and contracts and accounted for between 11% and 14% of total net sales during the same time period.

In 2020, we worked closely with public authorities and customers to launch products based on molecular technologies to test for the SARS-CoV-2 pathogen and the COVID-19 disease it triggers. We have built a comprehensive portfolio of solutions to cover the phases of the pandemic including: a collection of RNA extraction kits and automation instrumentation from our sample technologies portfolio, PCR testing workflows including QIAstat-Dx, NeuMoDx, and other PCR solutions, OEM components used by other diagnostic suppliers, antigen and antibody tests, and genomic solutions. We are fully mobilized to serve our customers in the pandemic response, providing existing solutions and developing a series of differentiated products. Dedicated COVID-19 solutions brought to market in 2020 include:

- QIAstat-Dx Respiratory SARS-CoV-2 Panel - a multiplex PCR test with EUA-authorization for the detection of SARS-CoV-2 plus more than 20 other respiratory pathogens;
- NeuMoDx - single-plex (also approved for saliva sample type) and multiplex;
- QIAprep&amp rapid PCR test - a solution that streamlines RNA extraction and PCR analysis into one process, delivering a result in under one hour and requiring less disposable laboratory plastic-ware than standard PCR tests, helping to avoid resource bottlenecks;
- QIAreach Antibody test - allows clinicians to detect immune status of individuals and has applications in determining vaccine efficacy;
- QuantiFERON SARS-CoV-2 T cell assay - enables researchers to explore longer-term immune responses to the virus and vaccines; and
- a suite of next generation sequencing (NGS) and bioinformatics tools - used for epidemiological studies.

QIAGEN Product Groups

Sample Technologies

Sample technologies is the first of our Five Pillars of Growth and includes products involved in the first step of any molecular lab process. Our broad portfolio of sample technologies includes consumables and instruments used in sample collection, stabilization, storage, purification and quality control. Some of our consumables are designed to run on our instruments, while others are universal kits designed for use with any molecular testing platform. These products are used in research and applied testing (forensics, human identification and food safety) laboratories as well as clinical testing.

Sample Technologies	Selected QIAGEN brands		
Primary sample technology consumables			
• Nucleic stabilization and purification kits designed for primary sample materials (DNA, RNA), manual and automated processing for genotyping, gene expression, viral and bacterial analysis	• QIAamp	• DNeasy	• RNeasy
	• PAXgene	• AdnaTest	• MagAttract
• Mainly based on silica membrane and magnetic bead technologies	• AllPrep	• QIAprep&amp	
Secondary sample technology consumables			
• Kits and components for purification of nucleic acids from secondary sample materials (e.g. gel, plasmid DNA)	• QIAprep	• QIAquick	• DyeEx
	• QIAGEN Plasmid	• QIAfilter	• R.E.A.L.
	• HiSpeed	• EndoFree	
Sample technology instruments			
• Instruments for nucleic acid purification, quality control and accessories	• QIAsymphony	• QIAcube Connect	• QIAcube HT
	• EZ1	• QIAxpert	• QIAxcel
	• TissueLyser		

Diagnostic Solutions

Diagnostic solutions include our molecular testing platforms and consumables covering three of our five pillars of growth, which are QuantiFERON, QIAstat-Dx and NeuMoDx, as well as Precision Medicine which involves companion diagnostic co-development revenues from projects with pharmaceutical companies, regulated assays and solutions for laboratory developed tests. Additional areas include Oncology and Sexual & Reproductive Health for detection of various diseases and for use in prenatal testing for detection of infectious diseases and for other laboratory processes.

Diagnostic Solutions	Selected QIAGEN brands		
Immune response consumables			
• Interferon-Gamma Release Assay (IGRA) for TB testing	• QuantiFERON	• QIAreach	
• Assays for post-transplant testing and viral load monitoring			
Oncology and Sexual & Reproductive health consumables			
• Assays for analysis of genomic variants such as mutations, insertions, deletions and fusions	• Therascreen	• Ipsogen	• digene HC2
• Assays for prenatal testing and detection of sexually transmitted diseases and HPV	• AmniSure / PartoSure		
Sample to Insight instruments			
• One-step molecular analysis of hard-to-diagnose syndromes	• QIAstat-Dx	• NeuMoDx	
• Fully integrated PCR testing			

PCR/Nucleic Acid Amplification

PCR/Nucleic Acid Amplification involves our research and applied PCR solutions and components. The product group includes another of our Five Pillars of Growth: QIAcuity. We offer optimized solutions for end-point PCR, quantitative PCR and digital PCR. Our kits, assays, instruments and accessories amplify and detect targets and streamline workflow for virtually any application.

PCR/Nucleic acid amplification	Selected QIAGEN brands		
Research PCR consumables			
• Different generations of PCR, quantitative PCR, 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 • OneStep RT-PCR • Type-it • OmniScript	• QuantiFast • QIAGEN Multiplex • miRCURY • miScript	• QuantiNova • HotStarTaq • TopTaq
Human ID/Forensics assay consumables			
• STR assays for Human ID, additional assays for food contamination	• Investigator (human ID / forensics)	• *mericon* (food safety)	
PCR instruments			
• Digital PCR solutions	• QIAcuity • Rotor-Gene Q	• QIAquant • QIAgility	• QIAamplifier 96
OEM consumables			
• Custom-developed and configured enzymes and PCR solutions that are sold to OEM customers	• Provided on an individualized contract basis		

Genomics/NGS

Genomics/NGS includes our universal NGS solutions as well as the full QIAGEN Digital Insights portfolio.

Genomics/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 Epitect	
QIAGEN Digital Insights solutions			
• Bioinformatics solutions analyze and interpret data to deliver actionable insights from NGS. This includes freestanding software or cloud-based solutions and is also integrated into many QIAGEN consumables and instruments	• QIAGEN Clinical Insight	• CLC Genomics Workbench	• QIAGEN Knowledge Base
	• N-of-One	• OmicSoft	• HGMD
	• Ingenuity Variant Analysis	• Ingenuity Pathway Analysis	
Custom laboratory and genomic services			
• Custom services such as DNA sequencing, whole genome amplification, and non-cGMP DNA production	• Provided on an individualized contract basis		

Other

Revenues from various sources including protein biology products, royalties, intellectual property and freight charges.

Principal Markets

We sell our products to more than 500,000 customers in two broad customer groups: Molecular Diagnostics (clinical testing) and Life Sciences (academia, pharmaceutical R&D and applied testing). We estimate the total addressable market has a volume of about $11 billion per year. The five pillars of growth – sample technologies, immune response, digital PCR, integrated PCR, syndromic testing – account for $6 billion of this total.

Molecular Diagnostics

The molecular diagnostics market includes healthcare providers engaged in many aspects of patient care that require accurate diagnoses and insights to guide treatment decisions in oncology, infectious diseases and immune monitoring.

We offer one of the broadest portfolios of molecular technologies for healthcare. 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 process tests reliably and efficiently, often handling hundreds of samples simultaneously. Our range of assays for diseases and biomarkers speed up and simplify laboratory workflow and standardize many lab procedures.

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 even before COVID-19 struck. The pandemic has demonstrated the value of molecular testing in healthcare and we expect the market to provide significant growth opportunities.

We have built a position as a preferred partner to co-develop companion diagnostics paired with targeted drugs. We have more than 25 master collaboration agreements with pharmaceutical industry customers, some with multiple co-development projects. They 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.

Molecular Diagnostics customers accounted for $904 million, $737 million, and $732 million of our sales in 2020, 2019 and 2018, respectively.

Life Sciences

The Life Sciences market includes governments and biotechnology companies – and researchers who use molecular testing and technologies and are generally served by public funding in areas such as medicine and clinical development, forensics and exploring the secrets of life.

We partner with customers across diverse disciplines in academia and industry, providing sample technologies, assay technologies, bioinformatics and services to universities and institutes, pharmaceutical and biotech companies, government and law enforcement agencies.

We provide 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. We often partner with leading institutions on research projects and develop customized solutions such as NGS panels for the digital sequencing of multiple gene targets.

In the course of the COVID-19 pandemic, we served increased demand from viral and vaccine researchers for RNA extraction, general PCR reagents and enzymes, and universal NGS solutions.

We are 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 in food safety and veterinary diagnostics. We provide 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.

We have 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 that are most likely to respond to particular therapies. We estimate that about half of our sales to these companies supports research, while the other half supports clinical development, including stratification of patient populations based on genetic information. Also, QIAGEN Digital Insights solutions are widely used to guide pharmaceutical research.

Life Sciences customers accounted for $966 million, $789 million, and $770 million of our sales in 2020, 2019 and 2018, respectively.

Competition

In sample technology products, 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 compete with other suppliers 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.

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 believe our competitors typically do not have the same comprehensive approach to sample to insight solutions as we do, nor do they have 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.

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.

Net Sales (in millions)	2020	2019	2018
Consumables and related revenues	$ 1,615.4	$ 1,354.1	$ 1,315.5
Instrumentation	254.9	172.3	186.4
Total	$ 1,870.3	$ 1,526.4	$ 1,501.8

Geographical Information

We currently market 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):

Net Sales (in millions)	2020	2019	2018
United States	$ 728.6	$ 663.9	$ 632.7
Other Americas	96.9	58.1	60.4
Total Americas	825.5	722.0	693.0
Europe, Middle East and Africa	682.3	487.5	490.3
Asia Pacific, Japan and Rest of World	362.6	317.0	318.5
Total	$ 1,870.3	$ 1,526.4	$ 1,501.8

We have built an increasing presence in key emerging markets as a growth strategy. In 2020, the top seven emerging markets - Brazil, Russia, India, China, South Korea, Mexico and Turkey - contributed approximately 15% of net sales.

Seasonality

Our business does not experience significant predictable seasonality. Historically, a significant portion of our sales has 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 that their activities are impacted by public health concerns such as the timing and severity of flu season.

Suppliers

We strive to ensure that our 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. Suppliers are subjected to a risk analysis with regard to environmental and social criteria based on their geographic location. Our procurement policy, which is available on our website, 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. In 2020, all new suppliers have signed our procurement policy. In addition, first-tier suppliers must confirm REACH, RoHS and conflict minerals compliance as appropriate.

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 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.

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 at 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. 902 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 QIAGEN 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 us in fast-growing fields of molecular testing, and generates 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 2020, we launched the QIAcuity digital PCR system which is designed to make digital PCR technology available to Life Sciences laboratories worldwide.

We collaborate with many institutions and companies to create innovative molecular solutions. In 2020, we partnered with Ellume, an Australian digital diagnostics company, to develop antigen and antibody tests. These tests provide rapid results through use of the QIAGEN eHub, which gives an automated read-out in less than 15 minutes.

Our QIAGEN 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 the 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.

We have 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.

My QIAGEN is an easy-to-use self-service portal that is personalized to our customers' needs and enables customers to manage different activities in one central place. Customers can now easily reorder, place bulk orders, apply quotes to their cart, and then track their order status. Functionality in the dashboard allows customers to monitor their instrument use and view the status of licenses and service agreements. Additionally, customers can access our exclusive content and services, such as webinars, handbooks and other documents.

Our GeneGlobe Design & Analysis Hub (www.geneglobe.com) is a valuable outreach to scientists in pharma and academia, enabling researchers to search and order from approximately 25 million pre-designed and custom PCR assay kits, NGS assay panels and other products. The new hub brings next-level experiment planning, execution and follow-up to life science researchers, linking our QIAGEN Digital Insights solutions with ordering of assays to accelerate research.

We use 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.

Intellectual Property, Proprietary Rights and Licenses

We have made and expect to continue to make investments in intellectual property. In 2020, additions to our intangible assets outside of business combinations totaled $24.0 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, 2020, we owned 368 issued patents in the United States, 284 issued patents in Germany and 1,813 issued patents in other major industrialized countries. We had 546 pending patent applications. Our policy is to file patent applications in Western Europe, the United States and Japan. Patents in most countries have a term of 20 years from the date of filing the patent application. We intend to aggressively prosecute and enforce patents and to otherwise protect our proprietary technologies. We also rely on trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

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

See “Risk Factors” included in Opportunities and Risks section of this Annual Report for details regarding risks related to our reliance on patents and proprietary rights.

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. The IVD Directive requires that medical devices meet the essential requirements set out in an annex of the Directive. These requirements include information about 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 applicable 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.

In May 2022, the Directive will be replaced by the In Vitro Diagnostic Device Regulation (IVDR) (EU) 2017/746 that was published in May 2017 and given a 5-year transition period until its full implementation on May 26, 2022. Unlike the Directive that specifies certain results that must be achieved by each Member State and permits each Member State to decide how to transpose the Directive into national law, the IVDR has binding legal force throughout every Member State and it will become effective on a set date in all the Member States. The major goals of the IVDR are to standardize diagnostic procedures within the EU, increase reliability of diagnostic analysis and enhance patient safety. Under the IVDR as enacted by the European Commission (EC), in vitro diagnostics will be subject to additional legal regulatory requirements after it comes into full effect. Among other things, the IVDR introduces a new risk-based classification system and requirements for conformity assessments. Products already certified by a Notified Body may remain on the market until 25 May 2024 under some conditions including fulfillment of specific requirements in the IVDR, but ultimately most products will have to be approved. Under the Directive nearly eighty (80) percent of QIAGEN products were under the self-declaration classification, while under IVDR nearly ninety (90) percent of QIAGEN products will require pre-approval, and those that are in the highest risk class will have to be tested by a Designated Reference Laboratory. In addition, there will also be a greater emphasis on post-market surveillance and submission of post-market performance follow-up reports.

With respect to the current COVID-19 pandemic, the EC has classified SARS-CoV-2 assays as high risk, and designated five (5) Notified Bodies under the IVDR, including QIAGEN's Notified Body, TÜV Rheinland. MedTech Europe has issued guidance in several areas, e.g., clinical benefit, technical documentation, state of art, accessories, and EUDAMED. Open points still being addressed/defined are the designation of EU Reference Laboratories and Common Specification for high risk IVDs.

United Kingdom

The UK's withdrawal from the EU will have major ramifications for IVD manufacturers that will, among other things have to follow new procedures that will apply in the UK including appointment of a UK Responsible Person rather than relying on European Authorized Representatives to manage their compliance efforts in the UK.

The UK Medicine and Healthcare Products Regulatory Agency (MHRA) issued a new guidance on how the country will regulate IVDs after January 1, 2021. According to MHRA, IVDs in the future will require certification in the UK, which is defined as England, Scotland and Wales, while companies will still be able to sell tests in Northern Ireland under existing EU IVD regulations. As described in the guidance, MHRA will continue to recognize CE marks until June 30, 2023. Companies wishing to place IVDs on the UK market will be required to register with MHRA after January 1, 2021, but will still be able to sell CE-IVD marked products for the next two-and-a half years. After July 1, 2023, companies selling in the UK will have to obtain a new marking called a UK Conformity Assessed mark (UKCA). More information about the new UK requirements should become available in the near future.

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. Congress has also signaled interest in clarifying the regulatory landscape for LDTs. In 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act was introduced in both chambers of Congress. If enacted, clinical laboratories that develop and offer LDTs and traditional IVD medical device manufacturers would be subjected to the same regulatory oversight. The VALID Act defines both LDTs and IVDs as in vitro clinical tests ("IVCT") and would establish a new regulatory framework under the Food, Drug and Cosmetic Act ("FDCA") for the review and oversight of IVCTs. The proposed regulatory framework adopts various concepts from the FDCA, utilizing a risk-based approach that aims to ensure that all marketed IVCTs have a reasonable assurance of both analytical and clinical validity.

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.

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 published a proposed rule which if finalized is intended to provide structure, clarity and transparency on the de novo classification process. In January 2021, it also published a final guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

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.

As a result of the COVID-19 pandemic, the US government declared a state of emergency which enabled the FDA to issue emergency use authorizations (EUAs) to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options. EUAs are in effect until the emergency declaration ends but can be revised or revoked as FDA considers the needs during the emergency and new data on a product's safety and effectiveness, or as products meet the criteria to become approved, cleared, or licensed by the FDA. Manufacturers of several types of SARS-CoV-2 assays have been granted EUAs, including QIAGEN. These authorizations are only intended for the duration of the emergency declaration, and afterwards will be revoked. The FDA has indicated the withdrawal of the EUA process will be done in a controlled ramp down.

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. 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 also noted that in some cases, if evidence is sufficient to conclude that the IVD companion diagnostic device is appropriate for use with a class of therapeutic products, the intended use/indications for use should name the therapeutic class, rather than each specific product within the class.

In April 2020, FDA published a final guidance entitled, "Developing and Labeling *In Vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products" that expands on that last issue in the 2014 final guidance and describes considerations for the development and labeling of *in vitro* companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products, when appropriate.

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

The FDA subsequently 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 that we develop 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.

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, the 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

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), established comprehensive federal standards for the privacy and security of health information. The HIPAA standards apply to three types of organizations: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically ("Covered Entities"). Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009. HITECH expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements for Covered Entities. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule (the "Omnibus Rule").

Under HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services (the "Secretary"). Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and, in some cases depending on the size of the breach, they must be reported through local and national media. Breach reports can lead to investigation, enforcement and civil litigation, including class action lawsuits.

We are currently subject to the HIPAA regulations and maintain an active compliance program that is designed to identify security incidents and other issues in a timely fashion and enable us to remediate, mitigate harm or report if required by law. We are subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To avoid penalties under the HITECH breach notification provisions, we must ensure that breaches of protected health information are promptly detected and reported within the company, so that we can make all required notifications on a timely basis. However, even if we make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In addition to the federal privacy and security regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to our clinical laboratories. Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. State requirements are particularly stringent regarding predictive genetic tests, due to the risk of genetic discrimination

against healthy patients identified through testing as being at a high risk for disease. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations, including genetic testing and genetic information privacy laws in all jurisdictions, both state and federal. However, these laws constantly change, and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security could result in civil and/or criminal penalties, significant reputational damage and could have a material adverse effect on our business.

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.

The General Data Protection Regulation ("GDPR"), which applies to all EU member states from May 25, 2018, also applies to some of our operations.

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, 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, the Office of Foreign Assets Control, and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

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 Statute 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. The U.S. Environmental Protection Agency (EPA) has also promulgated regulations setting forth importation, labelling, and registration requirements, among others, which may apply to certain products and/or establishments of the company.

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 major markets are adopting regulations and requirements similar to those of the 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 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 SE. Worldwide, we use SAP software to integrate most of our operating subsidiaries. Capital expenditures for property, plant and equipment totaled $132.8 million, $118.0 million and $109.8 million for 2020, 2019 and 2018, 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. In 2020, we made additional investments to expand production lines to meet both current demand as well as future growth. Our production capacity is increased through our manufacturing and research facilities in the United States. QIAGEN Sciences, LLC owns a 24-acre site in Germantown, Maryland. The 285,000-square-foot Germantown facility consists of several buildings in a campus-like arrangement and can accommodate over 500 employees. There is room for future expansion of up to 300,000 square feet of facility space. In 2020, we announced our plans to renovate the manufacturing facility to accommodate expanded production of testing products, including for COVID-19.

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 bioinformatics and 19,000 square feet in Minden, Nevada, for Service Solutions. We have shared service centers that lease facilities in Wroclaw, Poland, (65,100 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 our 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 we operate 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 2020, we consider the opportunities and risks manageable and the survival of QIAGEN not in danger. 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. 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 molecular technologies disseminate across two customer classes: Molecular Diagnostics and Life Science. 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. The value of diagnostics is above all being significantly enhanced by the COVID-19 pandemic and the dramatic increase in demand for testing solutions. 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. We evaluate organic growth opportunities each year as part of our 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 our 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 Report" section of this Annual Report) and the function of the Audit Committee of the Supervisory Board (discussed in more detail in the "Corporate Governance Report" section of this Annual Report). We maintain adequate internal controls over financial reporting to ensure the integrity of financial reporting, which is described further in the "Corporate Governance Report" section of this Annual Report. 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 this Annual Report.

	Risk Types
Base Business Risk	• Identification and monitoring of competitive business threats
	• Monitoring complexity of product portfolio
	• Monitoring dependence on key customers for single product groups
	• Reviewing dependence on individual production sites or suppliers
	• Evaluating purchasing initiatives, price controls and changes to reimbursements
	• Monitoring production risks, including contamination prevention, high-quality product assurance
	• Ensuring ability to defend against intellectual property infringements and maintain competitive advantage after expiration
Business Growth Risk	• Managing development and success of key R&D projects
	• Managing successful integration of acquisitions to achieve anticipated benefits
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 product approvals
	• Monitoring risks of FCPA (Foreign Corrupt Practices Act) or antitrust concerns arising from a network of subsidiaries and distributors in foreign countries

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

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, for example products in response to SARS-CoV-2. 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 competitor 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, software solutions and manufacturing capacity. 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 and our ability to scale manufacturing capacities to meet customer demands. Important product programs 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 for use with QIAGEN instruments or with "universal" automation systems and instruments, and bioinformatics solutions to analyze and interpret complex genomic data. In addition, in 2020 we launched the QIAcuity digital PCR series of platforms with fully-integrated solutions that simplify digital PCR workflows.

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, NeuMoDx and QIAcuity systems, 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 in recent years, with total net sales increasing to $1.87 billion in 2020 from $1.34 billion in 2016. We have made a series of acquisitions in recent years, including the acquisitions of NeuMoDx Molecular, Inc. in 2020, 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 increase 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 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. Potentially adverse changes that may come from the United Kingdom's exit from the European Union ("Brexit") are not fully 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.

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, our customers or us.

Our business involves operations around the world. Our primary 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 December 2019 outbreak of the novel coronavirus (COVID-19) and the resulting global pandemic. 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 we 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 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 in a timely manner or in sufficient quantities or qualities to produce certain products, and this could have an adverse impact on our results of operations.

We rely heavily 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 rely heavily 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.

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, financial flexibility or cash flow.

We rely on secure communication and information systems and are subject to privacy and data security laws which, in the event of a disruption, breach, violation or failure, could adversely affect our business.

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, as well as personally identifiable information of our customers and employees, in our data centers and on our networks or in the cloud. Our operations rely on the secure processing, storage and transmission of confidential and other information on both our own, or cloud-based, computer systems and networks. 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 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 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. In the U.S., individual states regulate requirements and have authority over privacy and personal data protection. 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 into and control over their personal information There are also European 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. As our activities continue to evolve and expand, we may be subject to additional laws that 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 subject us to costly regulatory action or lawsuits and could adversely impact our reputation, 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 encounter delays in receipt, or limits in the amount, of reimbursement approvals and public health funding, which may impact our ability to grow revenues in the healthcare market or 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. With evolving political realities in the United States, certain sections of the Patient Protection and Affordable Care Act of 2010 (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 extend 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 26% of our sales are generated by demand for use of our products at universities, government laboratories and private foundations, whose funding is dependent on 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 ensure 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.

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 the 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, could 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, China, India, South Korea, Mexico, Russia and Turkey, which together accounted for approximately 15% of total sales in 2020. 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 arising from 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 face 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 that 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 in order 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, this could adversely impact our results of operations, in particular our gross profit.

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 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.

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.

In the markets we serve, a high percentage of purchase orders are typically 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 on 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, 2020, we had outstanding long-term debt of $1.9 billion, of which $42.5 million was current. We may need to refinance these liabilities.

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 (Loss).

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 "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, 2020, our consolidated balance sheet reflected $2.4 billion of goodwill and $726.2 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, 2020, we owned 368 issued patents in the United States, 284 issued patents in Germany and 1,813 issued patents in other major industrialized countries. In addition, at December 31, 2020, we had 546 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.

Some 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. Since January 10, 2018, our shares have been 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 $55.27 to a low of $25.04. On the Frankfurt Stock Exchange our Common Shares have ranged from a high of €46.95 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, and does not intend 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 future stock repurchase programs.

QIAGEN has conducted share repurchase programs in the past through open-market transactions. 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, 2020, a total of approximately 228.0 million Common Shares were outstanding along with approximately 5.6 million additional shares reserved for issuance upon exercise or release of outstanding stock options and awards, of which 0.4 million were vested. A total of approximately 14.4 million Common Shares are reserved and available for issuances under our stock plans as of December 31, 2020, 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, convertible debt issued in 2020 and Warrants issued in connection with the Cash Convertible Notes cover an aggregate of 26.8 million underlying shares of common stock or up to a maximum of 42.5 million shares, 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, 2020, 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.

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 that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis, such as identifying the DNA of a virus or a mutation of a gene. QIAGEN 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 bioinformatics 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, 2020, we employed more than 5,600 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 September 2020, we acquired the remaining 80.1% of NeuMoDx, a company that designs and develops molecular diagnostic solutions for hospital and clinical reference laboratories. Prior to acquisition, we held a 19.9% investment in NeuMoDx and entered a strategic partnership in 2018 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. We distribute these systems in Europe and other markets outside the United States.
- In January 2019, we began developing next-generation systems for digital PCR and acquired the digital PCR assets of Formulatrix, Inc., a developer of laboratory automation solutions. In 2020, we began commercialization of fully integrated digital PCR solutions, combining QIAGEN technologies and automation with the Formulatrix assets we acquired. Known as QIAcuity digital PCR, the system offers 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. We paid Formulatrix $125.0 million in cash upon closing and paid $135.9 million during 2020 for the remaining milestone payments.
- Also in January 2019, we 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 our lead as the provider of the industry's largest genomics knowledge base.

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

Year Ended December 31, 2020, Compared to 2019

Net Sales

(in millions)	2020		2019		
Product type	**Net sales**	**% of net sales**	**Net sales**	**% of net sales**	**% change**
Consumables and related revenues	$ 1,615.4	86%	$ 1,354.1	89%	+19%
Instruments	254.9	14%	172.3	11%	+48%
Net Sales	$ 1,870.3		$ 1,526.4		+23%
Non-COVID-19 and COVID-19 products					
Non-COVID-19 products	$ 1,252.4	67%	$ 1,383.1	91%	-9%
COVID-19 products	617.9	33%	143.3	9%	+331%
Net Sales	$ 1,870.3		$ 1,526.4		+23%

In 2020, we experienced significant demand for solutions used in the COVID-19 pandemic and experienced improving trends in other areas of the business during the second half of 2020.

The instruments portfolio saw strong sales growth across multiple product categories including sample preparation platforms as well as general and integrated PCR equipment and platforms. Consumables and related revenues benefited from increased output of key consumable products including sample technologies kits and testing cartridges for QIAstat-Dx and NeuMoDx instruments. Net sales were positively impacted by two percentage points from favorable currency movements against the U.S. dollar.

(in millions)	2020		2019		
Customer class	**Net sales**	**% of net sales**	**Net sales**	**% of net sales**	**% change**
Molecular Diagnostics	$ 904.0	48%	$ 737.1	48%	+23%
Life Sciences	966.4	52%	789.3	52%	+22%
Net Sales	$ 1,870.3		$ 1,526.4		+23%
Product group					
Sample technologies	$ 803.9	43%	$ 548.4	36%	+47%
Diagnostic solutions	460.8	25%	465.5	30%	-1%
PCR / Nucleic acid amplification	363.6	19%	224.7	15%	+62%
Genomics / NGS	165.6	9%	183.8	12%	-10%
Other	76.6	4%	104.1	7%	-26%
Net Sales	$ 1,870.3		$ 1,526.4		+23%

Sample technologies were driven by strong growth in both consumables and instruments. Key drivers of this product group, which represents products involved in the first step in any molecular lab process, included COVID-19 solutions such as automated RNA extraction kits along with the launch of QIAprep&amp and improving trends in non-COVID products in the later portion of 2020.

Diagnostic solutions includes molecular testing platforms and products as well as Precision Medicine and companion diagnostic co-development revenues. This product group experienced growth due to sales of COVID testing solutions including QIAstat-Dx and NeuMoDx that was more than offset by the steep declines experienced earlier in 2020 for QuantiFERON-TB test sales that did see improving trends during the later portion of 2020 but finished the year down 21% compared to 2019.

PCR / Nucleic acid amplification involves research and applied PCR solutions and components and includes the QIAcuity digital PCR platform launched in September 2020. This product group was driven by strong growth across consumables and instruments in 2020 and also saw strong demand for OEM solutions and enzymes used in third-party diagnostic kits for COVID-19 testing.

Genomics / NGS includes universal NGS solutions as well as the full QIAGEN Digital Insights portfolio. This product group faced slower customer demand during the pandemic. Universal NGS sales were supported by initial orders of NGS-based kits used for epidemiological research of positive COVID-19 samples for viral variants during the second half of 2020.

Geographic region (in millions)	2020	2019	% change
Americas	$ 825.5	$ 722.0	+14%
Europe, Middle East and Africa	682.3	487.5	+40%
Asia Pacific, Japan and Rest of World	362.6	317.0	+14%
Net Sales	$ 1,870.3	$ 1,526.4	+23%

Top 7 emerging markets: Brazil, Russia, India, China, South Korea, Mexico and Turkey (2020: $287 million, 2019: $250 million, +14%)

EMEA led the geographic regions with 40% sales growth in 2020 due to strong performance in countries including France, the United Kingdom, Italy and Germany. EMEA was supported by one percentage point of sales growth from positive currency movements in 2020. Asia Pacific, Japan and Rest of World experienced gains during 2020 in China in part from strong QIAstat-Dx instrument sales as well as overall gains in other countries including Japan and Australia that more than offset a decline in South Korea particularly in QuantiFERON-TB tests. The Americas region benefited from significant increased demand in Brazil and Mexico throughout the year and gains in the United States in other areas of the portfolio more than offset the decline in QuantiFERON-TB tests for the full-year.

Gross Profit

(in millions)	2020	2019	% change
Gross Profit	$ 1,232.7	$ 1,005.3	+23%
Gross Margin	65.9%	65.9%	

Generally, our consumables and related products have a higher gross margin than our instrumentation products and service arrangements and fluctuations in the sales levels of these products and services can result in changes in gross margin between periods. Gross profit in 2020 includes the shift in product mix where lower margin instrument products advanced at a faster pace than consumable products as well as higher material costs. These adverse impacts were offset by lower amortization expenses related to developed technology and patent and license rights, which have been acquired in business combinations or asset acquisitions. The amortization expense on acquisition-related intangibles within cost of sales decreased to $63.2 million in 2020 from $71.5 million in 2019. The decrease follows the full amortization of assets previously acquired in 2007. We expect that our acquisition-related intangible amortization will increase as a result of the acquisition of NeuMoDx as further discussed in Note 5 *"Acquisitions and Divestitures"* and in the event of future acquisitions.

Operating Expenses

	2020		2019		
(in millions)	Expenses	% of net sales	Expenses	% of net sales	% change
Research and development	$ 149.1	8.0%	$ 157.4	10.3%	-5%
Sales and marketing	413.7	22.1%	391.9	25.7%	+6%
General and administrative	111.7	6.0%	112.3	7.4%	-1%
Acquisition-related intangible amortization	20.8	1.1%	30.0	2.0%	-31%
Restructuring, acquisition, integration and other, net	150.0	8.0%	199.8	13.1%	-25%
Long-lived asset impairments	1.0	0.1%	140.0	9.2%	-99%
Total operating expenses	$ 846.3	45.2%	$ 1,031.4	67.6%	
Income (loss) from operations	$ 386.4	20.7%	$ (26.1)	(1.7)%	

2020 results include the expenses from the discontinued tender offer while 2019 includes expense related to the decision to stop NGS instrument development and targeted efficiency improvement initiatives.

Research and Development

The overall decrease is the result of the suspended development of NGS-related instrument systems in connection with the 2019 restructuring measures discussed in Note 6 *"Restructuring"*. In 2020, additional costs include costs associated with QIAstat menu expansion, the launch of new products including QIAprep&amp and QIAcuity as well as costs incurred following the acquisition of NeuMoDx. 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. Further, business combinations, along with the acquisition of new technologies, may increase research and development costs in the future. We have a strong commitment to innovation and expect to continue to make investments in our research and development efforts.

Sales and Marketing

Sales and marketing expenses were primarily associated with personnel, commissions, advertising, trade shows, publications, freight and logistics expenses, and other promotional expense. Higher costs in 2020 reflect higher share-based compensation expense as a result of an increase in estimated performance achievement and increases in freight and commissions due to higher sales, partially offset from the lockdowns and limitations resulting from the COVID-19 pandemic, such as restricted travel and postponed trade shows and exhibits. When pandemic lockdowns and restrictions are lifted, we anticipate that absolute sales and marketing costs will increase along with new product introductions and growth in sales of our products.

General and Administrative

The decrease in general and administrative expenses reflects lower share-based compensation following the 2019 restructuring measures partially offset by continued investments in information technology systems, including cyber security, across the organization as well as an increase in the personnel expenses from performance achievements due to sales volume increases.

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 2020, amortization expense on acquisition-related intangibles within operating expense decreased to $20.8 million, compared to $30.0 million in 2019. The decrease follows the full amortization of assets previously acquired in 2007. Our acquisition-related intangible amortization will increase in the event of future acquisitions.

Restructuring, Acquisition, Integration and Other, net

Restructuring, acquisition, integration and other, net expenses totaled $150.0 million during the year ended December 31, 2020 and includes acquisition expenses related to the unsuccessful acquisition attempt by Thermo Fisher of $125.5 million, including a $95.0 million expense reimbursement. Additionally, we incurred net acquisition, integration and other expenses of $21.2 million, including charges for NeuMoDx as well as the $11.7 million gain on the value of our interest held on the acquisition date. We also incurred $3.3 million of charges related to the 2019 Restructuring program as discussed further in Note 6. As we continue the integration of NeuMoDx, we expect to incur additional integration costs in 2021.

During 2019, $199.8 million of restructuring, acquisition, integration and other, net expenses were incurred including $163.0 million for the 2019 Restructuring program. Additionally, we incurred net acquisition, integration and other expenses of $36.8 million, including charges for the 2019 acquisitions as well as a $7.4 million gain from the reduction in the fair value of contingent consideration.

Long-lived Asset Impairments

In 2020, $1.0 million impairments to property, plant and equipment were recorded and in 2019, $140.0 million impairments including both intangible assets and property, plant and equipment were recorded primarily in connection with the 2019 restructuring measures as further discussed in Note 6 "Restructuring and Impairments".

Other Income (Expense)

(in millions)	2020	2019	% change
Interest income	$ 10.0	$ 22.1	-55%
Interest expense	(71.3)	(74.2)	-4%
Other income, net	114.3	0.4	
Total other income (expense), net	$ 53.0	$ (51.6)	+203%

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" and other components including the interest portion of operating lease transactions. Interest income earned in 2019 included interest on higher cash balances following the issuance of cash convertible notes in November 2018.

Interest expense primarily relates to debt, discussed in Note 16 "Debt" in the accompanying consolidated financial statements. During 2020, the majority of the 2021 Notes were repaid and we issued new zero coupon convertible debt due in 2027.

Other income, net the for year ended December 31, 2020 includes a gain of $123.3 million for the sale of our investment in ArcherDX, $5.0 million of income from equity method investees and a total of $1.6 million in gains related to prior sales of assets. These gains were partially offset by $9.3 million in unrealized losses recognized for the change in fair market value of all marketable equity securities, $4.1 million net losses on foreign currency transactions and a $2.3 million loss from the sale of an equity security investment.

Other income, 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. This income was partially offset by impairments, including $4.8 million of impairments in non-marketable investments accounted for under the equity method and net losses on foreign currency of $5.7 million for the year ended December 31, 2019.

Income Tax Expense (Benefit)

(in millions)	2020	2019	% change
Income (loss) before income taxes	$ 439.5	$ (77.8)	+665%
Income tax expense (benefit)	80.3	(36.3)	+321%
Net income (loss)	$ 359.2	$ (41.5)	
Effective tax rate	18.3%	46.7%	

Our effective tax rates differ from The Netherlands statutory tax rate of 25% due in part to our operating subsidiaries being exposed to effective tax rates ranging from zero to 35%. 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 2020 and 2019, our effective tax rates were 18.3% and 46.7%, respectively. The comparison is impacted by pre-tax book income which was higher in 2020 reflecting higher operating income in the current year due to the significant demand for solutions used in COVID-19 testing. This compares to pre-tax book loss in 2019 which reflects the restructuring charges incurred during the third quarter of 2019. Additionally, we record partial tax exemptions on foreign income primarily derived from operations in Germany, the Netherlands and Singapore. These foreign tax benefits are due to a combination of favorable tax laws, rules, and exemptions in these jurisdictions, including intercompany foreign royalty income in Germany which is statutorily exempt from trade tax. Further, we have intercompany financing arrangements in which the intercompany income is nontaxable or partially exempt. During 2020, we have intercompany financing arrangements through Dubai, and through mid-2019 had arrangements through Luxembourg and Ireland.

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 “Opportunities and Risks” section.

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, net, and in 2020, 2019 and 2018 was $4.1 million, $5.7 million, and $12.3 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, 2020, we had cash and cash equivalents of $598.0 million and short-term investments of $117.2 million. As of December 31, 2019, we had cash and cash equivalents of $623.6 million, restricted cash of $5.7 million and short-term investments of $129.6 million. 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, 2020, cash and cash equivalents had decreased by $31.4 million from December 31, 2019, primarily as a result of cash used in investing activities of $443.3 million and cash used financing activities of $50.1 million, partially offset by cash provided by operating activities of $457.8 million. As of December 31, 2020 and 2019, we had working capital of $1.05 billion and $618.9 million, respectively.

Cash Flow Summary

(in millions)	2020	2019
Net cash provided by operating activities	$ 457.8	$ 330.8
Net cash used in investing activities	$ (443.3)	$ (222.3)
Net cash used in financing activities	$ (50.1)	$ (639.1)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	$ 4.2	$ 0.8
Net decrease in cash, cash equivalents and restricted cash	$ (31.4)	$ (529.7)

Operating Activities

For the years ended December 31, 2020 and 2019, we generated net cash from operating activities of $457.8 million and $330.8 million, respectively. While net income was $359.2 million in 2020, non-cash components in income included $205.0 million of depreciation and amortization, a gain of $121.8 million on sales of investments primarily related to the sale of the investment in ArcherDX as discussed in Note 10 "Investments", $42.3 million of amortization of debt discount and issuance costs and $40.9 million of share-based compensation expense. Operating cash flows include a net decrease in working capital of $130.2 million excluding changes in fair value of derivative instruments. The current period change in working capital is primarily due to increased inventories in order to meet the increase in demand and decreased accrued and other current liabilities following cash payments made in connection with the 2019 restructuring measures. 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 $443.3 million of cash was used in investing activities during 2020, compared to $222.3 million during 2019. Investing activities during 2020 consisted principally of $239.6 million in cash paid for acquisitions, net of cash acquired primarily for NeuMoDx, $171.5 million paid for intangible assets including $135.9 million of the remaining milestone payments for the digital PCR assets acquired from Formulatrix in 2019, $132.8 million in cash paid for purchases of property and equipment which includes the investments we are making in expanded production capacity, $53.4 million paid for collateral assets and $49.8 million for purchases of short-term investments. This was partially offset by $181.2 million from the sale of short-term investments and $25.6 million net proceeds from sales of investments in privately held companies as discussed in Note 10 "Investments".

Cash used in investing activities during 2019 includes $156.9 million paid for intangible assets primarily related to the asset acquisition from Formulatrix, $294.0 million for purchases of short-term investments and $118.0 million purchases of property, plant and equipment partially offset by $396.1 million from the sale of short-term investments.

Financing Activities

For the year ended December 31, 2020, cash used in financing activities was $50.1 million compared to cash provided by financing activities of $639.1 million in 2019. Financing activities during 2020 consisted primarily of net payments of $468.6 million in connection with the final conversion, redemption and termination of the 2021 Cash Convertible Notes and warrants as discussed further in Note 16 "Debt" as well as $64.0 million for repurchases of QIAGEN shares. This was partially offset by $497.6 million in proceeds from issuance of the 2027 Zero Coupon Convertible Notes.

In 2019, cash used in financing activities totaled $639.1 million primarily due to $506.4 million repayments of long-term debt and repurchases of QIAGEN shares totaled $74.5 million in 2019.

Other Factors Affecting Liquidity and Capital Resources

As of December 31, 2020, we carry $1.9 billion of long-term debt, of which $42.5 million is current.

In December 2020, we issued $500.0 million aggregate principal amount of zero coupon Convertible Notes due in 2027 (2027 Notes). The 2027 Notes will mature on December 17, 2027 unless converted in accordance with their terms prior to such date as described more fully in Note 16 "Debt".

In November 2018, we issued $500.0 million aggregate principal amount of Cash Convertible Senior Notes which is due in 2024 (2024 Notes). 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). 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 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 "Debt".

In December 2020, we obtained a €400 million syndicated revolving credit facility with a contractual life of three years with the ability to extend by one year two times. No amounts were utilized at December 31, 2020. The facility can be utilized in Euro and bears interest of 0.525% to 1.525% above EURIBOR, and is offered with interest periods of one, three or six months. The interest rate is linked to our environmental, social and governance (ESG) performance. We have additional credit lines totaling €27.0 million with no expiration date, none of which were utilized as of December 31, 2020.

In March 2014, we issued Cash Convertible Senior Notes of which $0.2 million remains outstanding as of December 31, 2020 and will be repaid at maturity on March 19, 2021.

In October 2012, we completed a U.S. private placement with three series at a weighted average interest rate of 3.66%. The following two series remain outstanding at December 31, 2020: (1) $300 million 10-year term due in 2022 (3.75%); and (2) $27 million 12-year term due in 2024 (3.90%).

In connection with certain acquisitions, we could be required to make additional contingent cash payments totaling up to $26.6 million based on the achievement of certain revenue and operating results milestones as further discussed in Note 20 "Commitments and Contingencies".

In May 2019, we announced our sixth share repurchase program of up to $100 million of our common shares. During 2020, we repurchased 1.3 million QIAGEN shares for $64.0 million (including transaction costs). This program ended in December 2020. Repurchased shares will be held in treasury in order to satisfy various obligations, which include employee share-based remuneration plans.

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

We believe that funds from operations, existing cash and cash equivalents, together with the proceeds from any 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

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, 2020, 2019 and 2018.

Contractual Obligations

As of December 31, 2020, our future contractual cash obligations are as follows:

Contractual Obligations	Payments Due by Period						
(in millions)	Total	2021	2022	2023	2024	2025	Thereafter
Long-term debt [1]	$ 1,980.0	$ 64.7	$ 505.3	$ 370.2	$ 578.9	$ 0.3	$ 460.7
Purchase obligations	250.8	199.8	42.6	5.4	3.0	-	-
Operating leases	117.0	25.4	21.0	16.3	10.8	6.7	36.9
License and royalty payments	30.0	10.0	7.2	4.5	2.6	2.3	3.4
Total contractual cash obligations	$ 2,377.9	$ 299.9	$ 576.1	$ 396.3	$ 595.3	$ 9.3	$ 501.0

[1] Amounts include required principal, stated at the current carrying values, and interest 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 $26.6 million based on the achievement of certain revenue and operating results milestones as follows:

(in millions)	
2021	$ 8.9
2022	17.7
	$ 26.6

Of the $26.6 million total contingent obligation, we have assessed the fair value at December 31, 2020 to be $23.6 million which is included in accrued and other current liabilities in the accompanying consolidated balance sheet.

Liabilities associated with uncertain tax positions, including interest and penalties, are currently estimated at $104.9 million as of December 31, 2020 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.

Human Resources

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 2020, QIAGEN had 5,610 full-time equivalent employees, an increase of 10% from 5,096 at the end of 2019.

Recognizing that our employees are the key to our success, we seek to be a great place to work. In 2020, we were once again recognized as a "Top Employer" in Germany by the Top Employer Institute, a global authority on recognizing excellence in people practices. Also in 2020, our subsidiary in Brazil was certified for the first time as a "Great Place to Work," and awarded one of the "Best Workplaces" in healthcare as well as Top 5 in diagnostic medicine. Finally, our U.S. headquarters in Germantown, Maryland, was awarded five different awards by the Alliance for Workplace Excellence (AWE), including the Workplace Excellence Seal of Approval, Diversity Champion Award, and Best Practices Supporting Workers 50+.

We are committed to creating an environment that is rich in diversity and empowers all employees. Diverse teams strengthen our organization through the variety of ideas, perspectives and approaches they bring to our business. Our teams outperform and succeed when they are composed of individuals with the widest possible range of personalities, backgrounds and traits. That's why we value each person's uniqueness and maintain an environment where all individuals can contribute to our success based on their strengths and characteristics. In 2020, our multicultural workforce was composed of at least 80 nationalities with an average age of 40.1. With 48% women, we are well balanced in terms of gender on an aggregate level. Our strategic initiative on gender diversity, which began in 2018, has yielded remarkable results in the past years, particularly with regard to leadership positions. The participation of women in leadership roles rose from just under 28% in 2018 to just under 32% in 2020 as a result of a series of initiatives to drive awareness, engagement, and development of this area among our leadership team.

Employee development is viewed as integral to the success of creating lasting value for our customers, patients, colleagues, partners, and shareholders. We offer 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 lives everywhere in the world. We offer various training platforms that provide 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, compliance, competencies and leadership development. In 2020, we ran a mix of virtual instructor-led and e-learning courses. All in person trainings were put on hold in 2020 due to the COVID-19 pandemic.

Internal and external ratings have improved significantly and support our preferred position in the global working environment. Specific retention targets have been met with a 9% voluntary turnover rate for the total workforce and a voluntary turnover rate of 5% for the management level in 2020.

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. We participate in various compensation benchmarking surveys that provide information on the level and mix of compensation awarded by 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. Furthermore, to align our compensation programs with the interests of shareholders, management levels receive a portion of their total compensation in the form of long-term compensation, which is granted as equity as a reward for performance.

In 2020 as a consequence of the global pandemic, a large portion of our employees worked remotely beginning in the first quarter of 2020 and continuing throughout the year. For our essential workers and in our locations where a small number of employees continued to work on site, we implemented safety measures including routine on-site testing at critical manufacturing facilities to reduce the risk of COVID-19 transmission.

Employees worldwide

	2018	2019	2020
Americas	1230	1132	1328
EMEA	2670	2820	3059
APAC & RoW	1052	1144	1223
Total	4952	5096	5610

2018

Production	22%
R&D	21%
Sales	40%
Marketing	6%
Admin	11%

2019

Production	23%
R&D	19%
Sales	40%
Marketing	6%
Admin	12%

2020

Production	28%
R&D	16%
Sales	39%
Marketing	6%
Admin	11%

Future Perspectives

QIAGEN Perspectives for 2021

With a differentiated portfolio of Sample to Insight solutions for molecular testing, QIAGEN announced in February 2021 that it expects an 18-20% rise in sales (at constant exchange rates, CER) in 2021 and adjusted earnings per share (EPS) to increase to $2.42-2.46 (CER) from $2.15 in 2020. We estimate the total addressable market at about $11 billion per year. QIAGEN's five pillars of growth – Sample technologies, QuantiFERON, QIAcuity digital PCR, NeuMoDx, QIAstat-Dx – account for more than $6 billion of this total.

QIAGEN expects its 2021 results to reflect both the ongoing strong demand for COVID-19 test solutions during the course of the first half of the year as widespread vaccines are expected to be available by the middle of 2021 as well as continued improvements in non-COVID-19 areas of its portfolio throughout the year. These expectations are also based on plans for significant investments in R&D and clinical trials to strengthen the competitive profile of QIAGEN's five pillars of growth. In particular, the company is planning initiatives to expand the test menu for the NeuMoDx and QIAstat-Dx automated PCR systems in the U.S. and Europe.

As vaccination programs gain traction around the world, the demand for COVID-19 testing is expected to change. QIAGEN anticipates demand for PCR and antigen testing solutions to continue during the first half of 2021, but could recede to a lower level during the second half. This outcome depends significantly on the impact of new viral variants. QIAGEN plans to continue investing in upscaling its production lines which are serving pandemic testing demands as well as supporting future growth of many products for non-COVID applications.

QIAGEN is encouraged for the future as it continues to serve COVID-19 testing demands while capturing strong growth opportunities in non-COVID related applications once the pandemic has been brought under control. The company is managing the increase in demand for non-COVID categories and planning for a steady sales increases as clinical testing volumes return for oncology and infectious diseases and research activities resume in academia and pharma projects. The company is focused on investments in its five pillars of growth to fuel its success beyond the pandemic and create long term shareholder value. QIAGEN aims to maintain our leading position in sample technologies, grow the QuantiFERON franchise anchored by its tuberculosis test, expand the QIAcuity digital PCR platforms and the NeuMoDx integrated PCR systems for clinical diagnostics, and drive the use of the QIAstat-Dx syndromic testing platform.

Global Economic Perspectives for 2021

The world economy entered a recession in 2020 as the COVID-19 pandemic took hold, but is now expected to grow again in 2021 as vaccination programs strengthen economic activity, especially in developed countries. In January 2021, the International Monetary Fund said the world economy would grow 5.5 percent this year, while the World Bank forecast a 4 percent annual increase. However, considerable pandemic-related risks mean any outlook is unusually uncertain: unforeseen changes to lockdown measures, vaccine rollouts, and general financial conditions and commodity prices could hamper – or boost – growth more than expected. Aside from indications that vaccination programs will gain pace this year, fiscal stimulus measures across major economies and a continuation of accommodative monetary policy by central banks are expected to underpin a positive economic development. But, even then, recovery is expected to be subdued and challenging. Economic momentum tends to benefit our performance, while downturn can limit spending by customers. Currency exchange rates also positively or negatively affect the company's results as these are reported in U.S. dollars.

Industry Perspectives for 2021

The demand for testing for active SARS-CoV-2 infections using PCR and antigen products is expected to decline to a lower base level as vaccination programs increase during the year. Viral immune-response monitoring using T-cell and antibody testing may increase along with population monitoring to stop new infection hotspots and multiplex PCR tests to discern between COVID-19 and other respiratory illnesses.

PCR testing volumes are expected to remain fairly robust in 2021. With COVID-19 hospitalizations expected to decrease during the year, elective procedures and laboratory volumes for non-COVID-19 issues are likely to recover – although some industry observers expect global demand trends to only normalize again in 2022.

The pandemic has cemented the trend of genomic insights moving rapidly from basic research laboratories into applications in medicine and other fields, delivering ever-greater value for patients and other users. As innovation drives market expansion, QIAGEN has a dynamic opportunity to continue its growth in 2021 and the years beyond.

COVID-19 has drawn attention to the fact that molecular testing can also evaluate and monitor patients for cancer, infectious diseases and other conditions. Molecular medicine is migrating from research-based institutions to hospitals and reference laboratories in need of quick, accurate results, increasing the demand for standardized tests and automated workflows. Customers embrace diverse technologies based on different settings and needs – from low-throughput to high-throughput, and from single-target or multiplex PCR analysis to in-depth next-generation sequencing. Customers increasingly want easy-to-use technologies that can also be used outside of a laboratory.

Life science researchers in Academia and the Pharma industry rely on novel sample and analytical technologies to explore disease pathways and biomarkers, and also to guide drug development and clinical trials. Genomic insights from molecular biology laboratories are increasingly leading to new drug approvals. Applications of molecular testing also are expanding for public safety needs such as forensics and environmental monitoring.

QIAGEN engages with customers across the continuum from discovery to routine molecular testing and aims to create value with differentiated solutions and automation systems that make improvements in life possible.