Management Report

Management Report

Business and Operating Environment

QIAGEN is a global leader in Sample to Insight solutions that transform biological samples into valuable molecular insights. Our mission is to enable customers across the continuum of molecular research and clinical testing to unlock valuable insights faster, better and more efficiently - from the raw biological sample to the final interpreted results. 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 (Polymerase Chain Reaction) 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. The SEC maintains an Internet site that contains reports and other information regarding issuers that file electronically with the SEC. The address of that site is www.sec.gov. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this Annual Report. We have included our website address in this document solely as an inactive textual reference.

Totals within tables presented in U.S. dollar millions may contain rounding differences.

Operating Environment

Economic Environment

The global economy grew approximately 6% in 2021, reflecting the continued impacts of the COVID-19 pandemic. During 2021, legislators in advanced economies and central banks around the world took action to stabilize the economy and provide liquidity to market participants amid the spread of COVID-19 variants throughout the world. Vaccine-powered recoveries in some regions and continued adaptation of economic activity where pandemic restrictions remain have been balanced against emerging markets and developing economies that did not yet have access to wide-scale vaccine programs. On the other hand, the global economic expansion in 2021 is compared against record lows of economic activity in 2020 during the initial stages of the pandemic due to shutdowns across the globe. After ending down 7% in 2020, the U.S. Dollar Index, which tracks the currency's value against other major currencies, was up 7% at the end of 2021.

Industry Environment

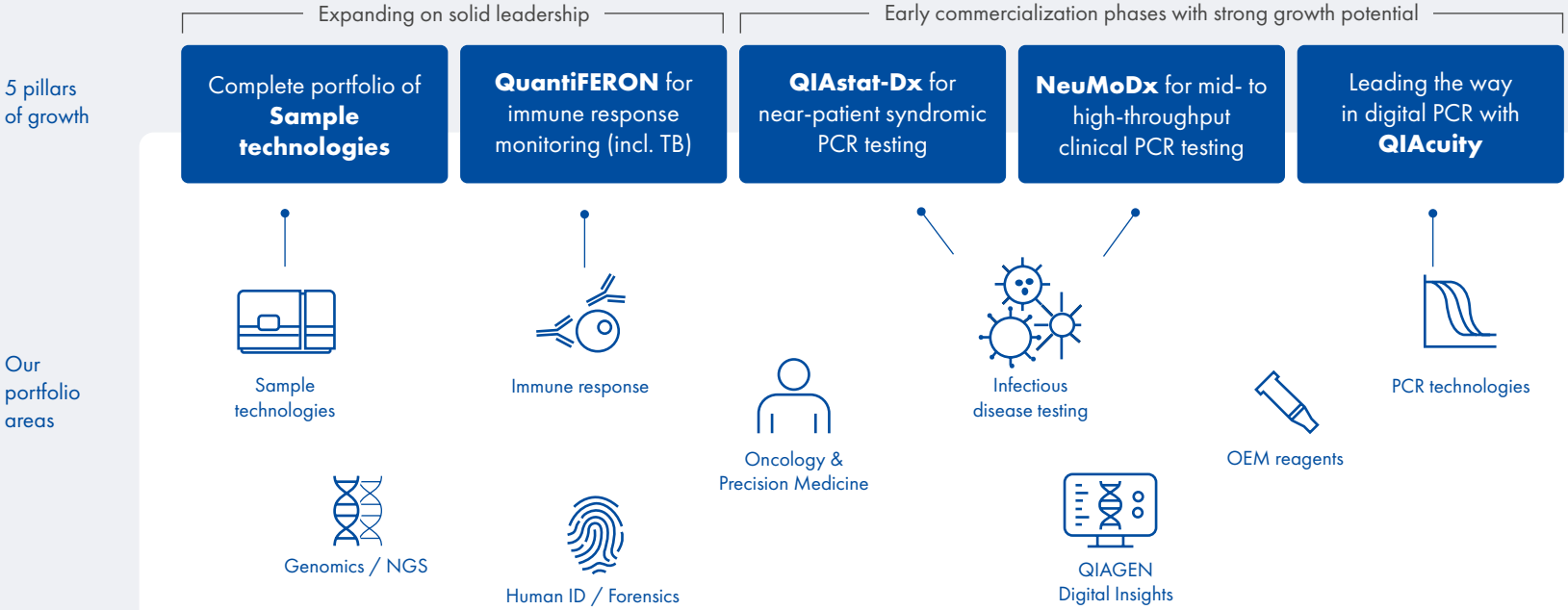
The molecular diagnostics market grew due to increased funding by federal bodies and the private sector during the year as the COVID-19 pandemic continued. In 2020, the expanding use of polymerase chain reaction (PCR), antigen, antibody and T-cell testing significantly raised public awareness of molecular diagnostics and its potential beyond the pandemic. During 2021, there was an increase in demand for both testing equipment as well as the availability of wide-scale testing options in many regions of the world. Surveillance of COVID-19 variants and population immunity became a growing topic as vaccinations were rolled out in many countries. To support this, technologies for NGS and PCR continued to evolve, making molecular testing more accessible, faster and more efficient.

As lockdowns eased, the increase of in-person activities led to additional demand for insights in diagnostics, life science research, pharmaceutical R&D and public safety. The field of molecular diagnostics continues to expand into new areas of medicine – enabling clinicians to evaluate and monitor cancers, infectious diseases, immune status, and prenatal or neonatal health. The expansion 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 in molecular testing from beginning to end.

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.

We focus on areas to build and maintain leading positions



In 2021, we continued to expand our portfolios with solutions used in COVID-19 testing as well as non-COVID related applications.

For COVID-19, 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, Original Equipment Manufacturer (OEM) components used by other diagnostic suppliers, antigen and antibody tests, and genomic solutions. New products in 2021 were focused on expanding our solutions for surveillance and providing products for rapid high-throughput PCR testing:

- artus® SARS-CoV-2 Prep&Amp UM Kit - solution for large-scale COVID-19 testing with CE-IVD registration
- QIAstat-Dx Respiratory 4 Plex Flu A-B/RSV/SARS-CoV-2 test - launched as CE-IVD test to identify whether patients have influenza A or B, respiratory syncytial virus (RSV) or SARS-CoV-2
- NeuMoDx™ Flu A-B/RSV/SARS-CoV-2 Vantage Test - launched as FDA approved test to identify whether patients have influenza A or B, respiratory syncytial virus (RSV) or SARS-CoV-2
- QuantiFERON SARS-CoV-2 assay - received CE-marking as an aid to assessment of immunity in vaccinated individuals
- QIAcuity digital PCR wastewater testing workflow - completed US government contract for use in wastewater testing
- PreAnalytix PAXgene Saliva Collector - new method of sample collection for SARS-CoV-2 research. Additional applications are being developed for the sample collection kit, including DNA
- QIAseq DIRECT SARS-CoV-2 Kit - Ultra-Fast sequencing solution for high-throughput genomic surveillance

In our non-COVID product groups, we continued to build menus and release new products to expand our capabilities and prepare our platforms to capture growth in a post-pandemic market.

Consumables launches:

- QIAwave product line - environmentally friendly sample preparation consumables kits
- QIAstat-Dx panels for the diagnosis of more than 20 various conditions through one syndromic test
  - Meningitis / Encephalitis - received CE-IVD registration
  - Gastrointestinal - submitted for US regulatory clearance
- QIAreach QuantiFERON-TB test - designed for use for the detection of TB in low-resource, high-burden countries (Approved by the Global Fund's Expert Review Panel Diagnostics (ERPD))
- QuantiFERON LIAISON® LymeDetect® assay - test for the early diagnosis of Lyme Borreliosis, a bacterial disease that can cause long-term and debilitating health issue, co-developed and commercialized with DiaSorin

Instrument launches:

- EZ2 Connect - next generation of the EZ1 sample processing instrument for applications including biomedical research, forensics and clinical diagnostics
- QIAcube Connect MDx - sample processing instrument cleared for use in US, EU and other worldwide markets
- QIAsphere - cloud-based solution to enable remote digital monitoring of instrumentation platforms, initially for QIAstat-Dx

Emerging stronger from a time of change

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 • Mainly based on silica membrane and magnetic bead technologies	• QIAamp • PAXgene • AllPrep	• DNeasy • AdnaTest • QIAprep&amp	• RNeasy • MagAttract
Secondary sample technology consumables			
• Kits and components for purification of nucleic acids from secondary sample materials (e.g. gel, plasmid DNA)	• QIAprep • QIAGEN Plasmid • HiSpeed	• QIAquick • QIAfilter • EndoFree	• DyeEx • R.E.A.L.
Sample technology instruments			
• Instruments for nucleic acid purification, quality control and accessories	• QIAsymphony • EZ1 • TissueLyser	• QIAcube Connect • QIAxpert	• QIAcube HT • QIAxcel

Sample technologies: The foundation of QIAGEN

A portfolio that has grown to address the complete spectrum of processing biological samples

Selected biological samples

- ✓ Tissue
- ✓ Cells
- ✓ Blood
- ✓ Serum
- ✓ Plasma
- ✓ Urine
- ✓ Stool
- ✓ Saliva
- ✓ Other body fluids
- ✓ Bone
- ✓ Plants
- ✓ Soil

Input demands
Low / high-volume
Low-quantity
High-quantity
Tubes / plates

Processing
Manual

Automated
Low-to
High-throughput

Target analytes
Genomic DNA
Plasmid DNA
cfDNA
mRNA,rRNA
miRNA
Proteins
Circ. Tumor cells

Applications

- ✓ Cloning
- ✓ DNA amplification
- ✓ Arrays
- ✓ Gene editing
- ✓ Epigenetic
- ✓ Cellular analytics
- ✓ qPCR / dPCR
- ✓ Sequencing / NGS
- ✓ Liquid biopsy
- ✓ Micobiome
- ✓ Gene silencing
- ✓ Proteomics

>200,000 publications referencing QIAGEN sample prep

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: QuantiFERON gold standard for modern latent TB-testing

Fully automated workflow for large-scale testing needs

DiaSorin LIASON XS & XL

> 8,000 systems Worldwide

QuantiFERON differentiation

- Full automation capability
- Highly specific
- No inter-reader variability
- Electronic results
- Quality-assured laboratory test[1]

[1]Not available in all markets

QIAreach – TB CE-IVD

Expanding access to high disease burden, low-resource areas

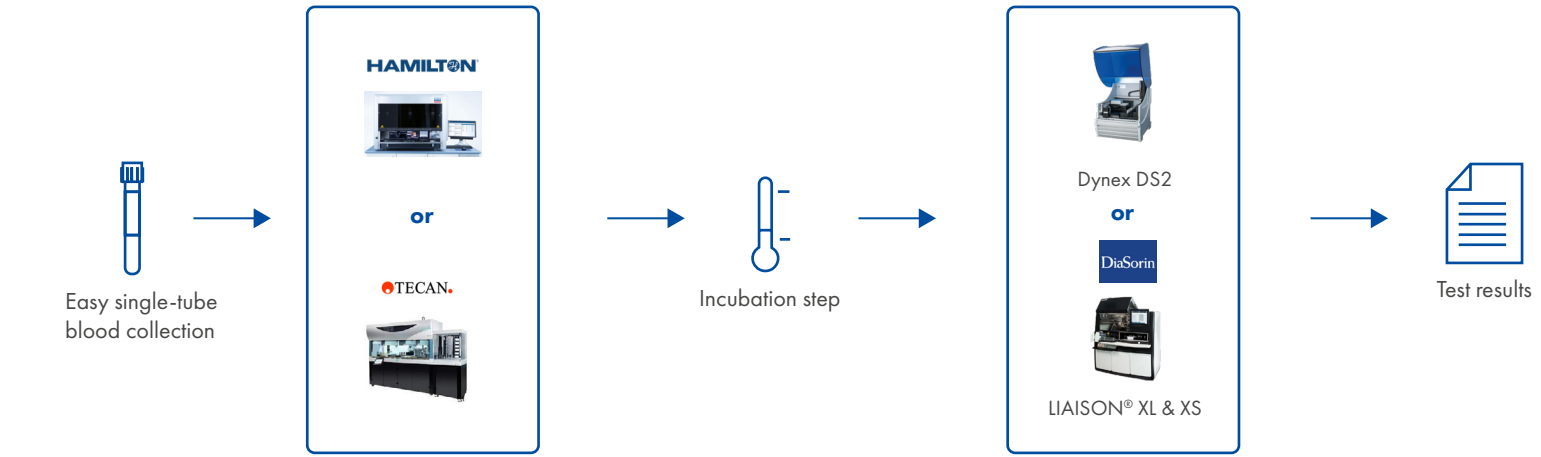
Portable
No cold chain required, all equipment <1 kg

No maintenance
No eHub maintenance or calibration

Battery powered
Requires no continuous external power

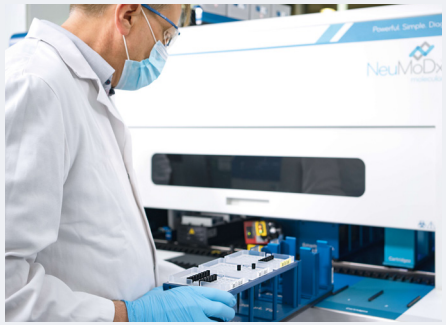
Scalable
1 to 8 samples, up to 24 samples per hour

No calibration or maintenance needed
No computer needed
No continuous power supply needed
No cold chain for consumables



Diagnostic solutions: NeuMoDx for mid- to high-throughput clinical testing

Bringing simplicity of clinical chemistry to integrated PCR testing



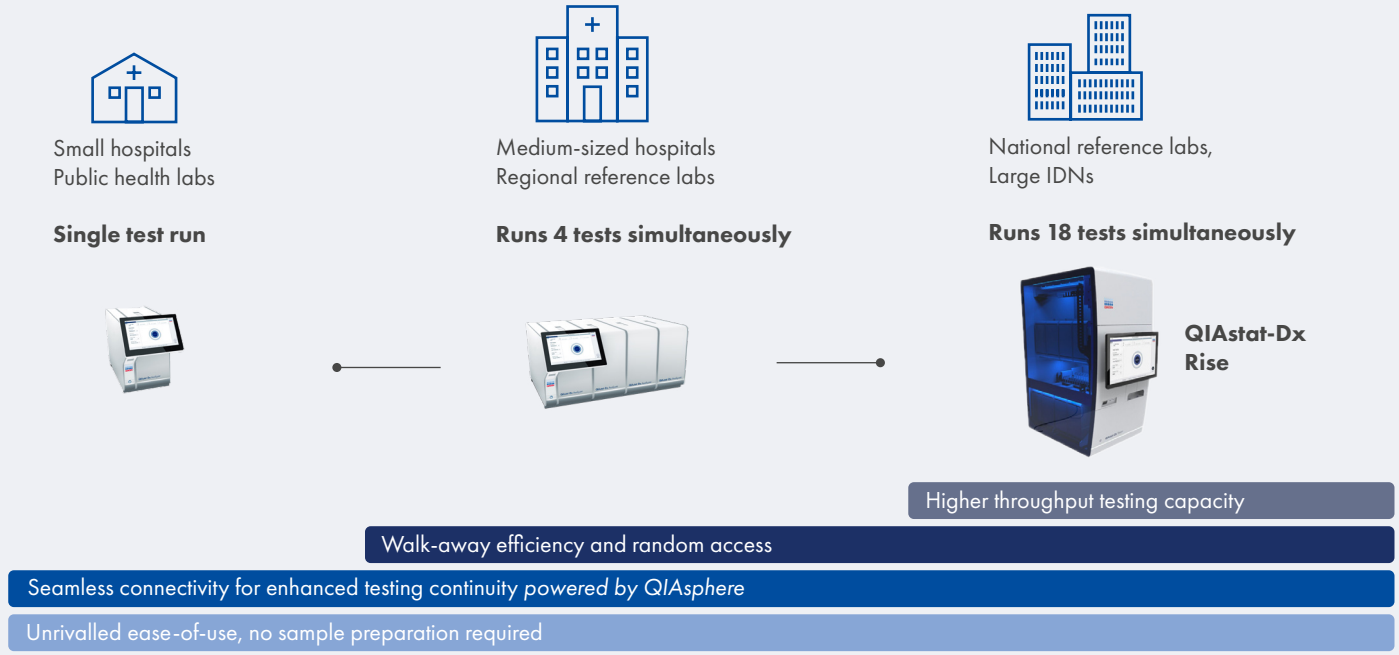
- High throughput
- Ultra-fast results
- Regulated and LDTs in parallel
- True random access
- Cost efficiency

Fully integrated microfluidic design

- No moving parts
- Containment of all waste
- Fewer plastic disposables

Self-contained cartridge

Diagnostic solutions: QIAstat-Dx for near-patient syndromic testing

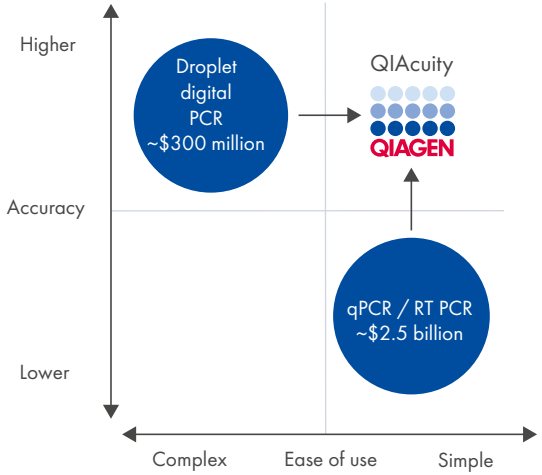


Diagnostic solutions	Selected QIAGEN brands		
Immune response consumables			
• Interferon-Gamma Release Assay (IGRA) for TB testing • Assays for post-transplant testing and viral load monitoring	• QuantiFERON	• QIAreach	
Oncology and Sexual & Reproductive health consumables			
• Assays for analysis of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

PCR / Nucleic Acid Amplification

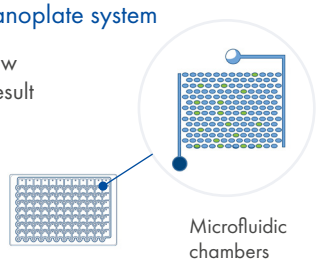
PCR / Nucleic Acid Amplification involves our research and applied PCR solutions and components. The product group includes another of our five pillars of growth: QIAcuity. We offer optimized solutions for end-point PCR, quantitative PCR and digital PCR. Our kits, assays, instruments and accessories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

PCR / Nucleic acid amplification: QIAcuity digital PCR accessing the comprehensive PCR market



Differentiated nanoplate system

Simplified workflow offers sample to result in **under 2 hours**



Complete portfolio for research use

New partnerships expanding breadth of applications

ATILA BioSystems — Non-invasive prenatal testing

GT MOLECULAR — Wastewater testing

ACTOME — Proteomics testing

Easy-to-use system vs. competition

Scalable	More versatile	Easier	Faster
Greater flexibility	Higher multiplexing	Fully automated workflow	Over twice as fast time-to-result

Millions of assays available on QIAGEN GeneGlobe portal

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

This product group includes our universal NGS (next-generation sequencing) solutions for use with any NGS sequencer as well as the full bioinformatics portfolio offered by QIAGEN Digital Insights.

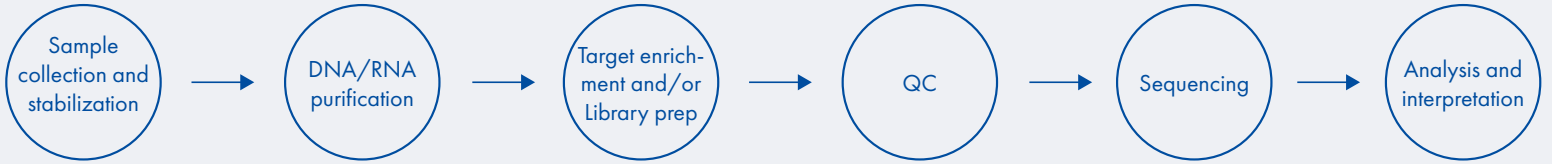
NGS / Genomics: Universal consumables providing high-performance chemistry

Target enrichment and streamlined library preparation leveraging leading sample preparation and bioinformatics

QIAGEN NGS differentiation
Superior technology performance for target enrichment
Gold standard RNAseq products for miRNA and RNA removal
Integrated with leading sample preparation and bioinformatics

NGS research market
>$800m market
>15% CAGR

Over **1 million** cancer samples analyzed



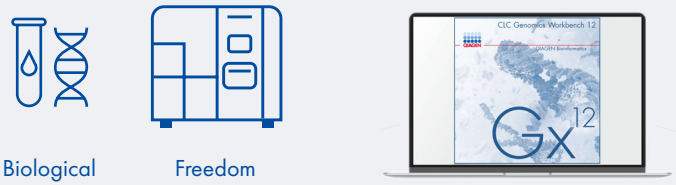
QIAGEN sample preparation

QIAseq Universal NGS solutions Compatible with any sequencer

QIAGEN Digital Insights Compatible with any sequencing data

NGS / Genomics: Bioinformatics serving the research community

Example: Analyzing gene expression data from Sample to Insight with QIAGEN Digital Insights



Biological sample

Freedom of choice

Sample to data

NGS library prep Sequencing

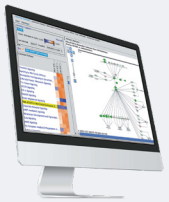
- Platform and Assay agnostic
- Whole transcriptome, Single Cell experiments

Data to information

Normalization and QC
Read mapping
Gene expression

QIAGEN CLC Genomics Workbench, Server and Cloud Engine

Per sample Analysis Portal, BaseSpace Integration



Information to knowledge

Data Integration
Metadata exploration
Differential expression

- **QIAGEN OmicSoft Server and Land Explorer**

Curated Experiments (OncoLand, DiseaseLand, GeneticsLand, Single Cell Land)

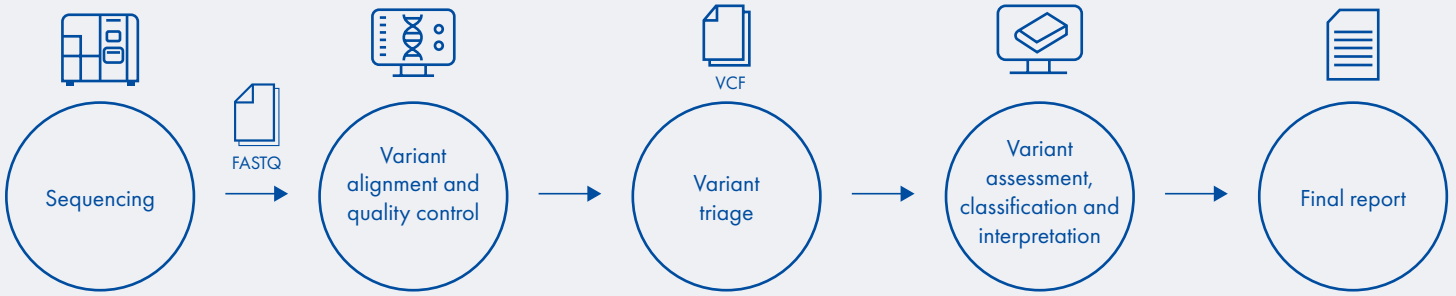
Knowledge to insight

Interpretation Pathway analysis

QIAGEN Ingenuity Pathway Analysis

NGS / Genomics: Bioinformatics serving clinical diagnostics

Software platform for scalable, standardized and reproducible variant interpretation



ONCOLOGY		**QCI PRODUCTS**
Clinical Testing Labs	Freedom of choice	← Precision Insights – QCI Interpret – QCI Interpret One →
Clinical Research Workflows	Freedom of choice	← QCI Translational →
Clinical Research databases	Freedom of choice	COSMIC-HSMD

HEREDITARY		**QCI PRODUCTS**
Clinical Testing Labs	Freedom of choice	← QCI Interpret →
Clinical Research Workflows	Freedom of choice	← QCI Translational →
Clinical Research databases	Freedom of choice	HGMD

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 • N-of-One • Ingenuity Variant Analysis	• CLC Genomics Workbench • OmicSoft • Ingenuity Pathway Analysis	• QIAGEN Knowledge Base • HGMD
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 over $11 billion per year. The five pillars of growth – sample technologies, immune response, digital PCR, integrated PCR, syndromic testing – account for more than $6 billion of this total.

Molecular Diagnostics: Improving outcomes for patients

~$6 billion
addressable market

QIAGEN value

- 2021 sales of ~$1.1 billion
- Focused on high-growth, high-demand opportunities
- Strong automation portfolio with multi-year assay menu expansion underway

Selected QIAGEN products

Sample technologies

- Tissue
- Blood
- Liquid biopsy
- Swabs, other

Assay technologies

Indication areas
- Oncology
- Immune modulation
- Infectious diseases technologies: QFT, PCR, NGS

Instruments

- QIAstat-Dx
- NeuMoDx
- QIAsymphony RGQ

Bioinformatics

QIAGEN Clinical Insight (QCI)
- Hereditary diseases
- Somatic and germline cancers
- All diseases

Life Sciences: Enabling the advancement of science

~$5 billion
addressable market

QIAGEN value

- 2021 sales of ~$1.1 billion
- Recognized innovator supporting breakthrough science
- Ability to translate innovations into commercial products

Selected QIAGEN products

Sample technologies

- ~300 different kit types
- Liquid biopsy, tissue, blood, cells, plants, microbiome, other

Assay technologies

- Real-time PCR
- Digital PCR
- Next-generation sequencing

Instruments

- QIAsymphony
- QIAcube Connect
- QIAcuity digital PCR
- RotorGene Q

Bioinformatics

- Ingenuity Pathway Analysis (IPA)
- Genomics Workbench / Server
- Microbial Pro Suite / RNA-seq
- Microbial Epigenetics

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. 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 and have created a rich pipeline of molecular tests that are transforming the treatment of cancer and other diseases. We have more than 25 master collaboration agreements with pharmaceutical industry customers, some with multiple co-development projects. In 2021 we continued to expand on these partnerships with new agreements to develop NGS based assays. These include partnerships

with Inovio for development of an assay for advanced cervical dysplasia, with OncXerna Therapeutics for their ovarian cancer therapeutic and with Sysmex Corporation for liquid biopsy oncology solutions. In addition we signed an agreement with Mirati for a PCR-based assay for Non-Small Cell Lung Cancer. Companion diagnostics move through clinical trials and regulatory approvals, along with the paired drugs, to commercialization and marketing to healthcare providers.

Molecular Diagnostics customers accounted for $1.1 billion, $904 million, and $737 million of our sales in 2021, 2020 and 2019, respectively.

What does Sample to Insight look like in Molecular Diagnostics?

A patient blood sample is collected using QIAGEN's proprietary blood collection tubes

QIAGEN's QuantiFERON-TB Gold Plus assay is used to analyze for latent infections with *M. tuberculosis* bacteria

Test results are delivered with one visit and in less than 24 hours

More than

100 million

QuantiFERON TB tests have been completed in the global fight against TB

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 building blocks 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 $1.1 billion, $966 million, and $789 million of our sales in 2021, 2020 and 2019, respectively.

What does Sample to Insight look like in the Life Sciences?

Wastewater samples are collected and brought to a lab, where RNA and DNA are extracted with QIAGEN kits and instrument

QIAGEN's QIAcuity digital PCR system is used to analyze target sequences

QIAGEN bioinformatics are used to analyze the data to monitor for new infectious disease outbreaks

70%

of all U.S. states are using QIAcuity for ultra-sensitive wastewater detection of SARS-CoV-2 infections

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 with a focus on the most attractive developed and emerging markets

Our global and regional headquarters

Venlo
Netherlands — Global HQ

Germantown
Maryland — Americas HQ

Hilden
Germany — EMEA HQ

Shanghai
China — Asia-Pacific HQ

Distribution partners in over **60** countries

35 subsidiaries

in over **25** countries

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)	**2021**	2020	2019
Consumables and related revenues	$1,986.3	$1,615.4	$1,354.1
Instrumentation	265.3	254.9	172.3
Total	**$2,251.7**	**$1,870.3**	**$1,526.4**

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)	**2021**	2020	2019
United States	$909.7	$728.6	$663.9
Other Americas	97.7	96.9	58.1
Total Americas	1,007.4	825.5	722.0
Europe, Middle East and Africa	814.4	682.3	487.5
Asia Pacific, Japan and Rest of World	429.9	362.6	317.0
Total	**$2,251.7**	**$1,870.3**	**$1,526.4**

We have built an increasing presence in key markets as a growth strategy. In 2021, the top seven growth markets - Brazil, Russia, India, China, South Korea, Mexico and Turkey contributed approximately 14% 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 viral infections such as the influenza or SARS-CoV-2 viruses.

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 2021, 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. In 2021, we have been able to secure a stable supply of chemicals, bioreagents, plastics and packaging materials with only moderate price adjustments. However in electronics, we have seen shortages that needed to be mitigated with long term contacts and high volume agreements, which at times included price increases. These increases are considered in the pricing of our products. We strive to maintain inventories at a sufficient level to ensure reasonable customer service levels, to guard against normal volatility in availability and we continue to work to circumvent shortages and keep pricing competitive.

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. 992 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 (NGS) kits to support our universal NGS franchise and our in vitro diagnostics partnership with Illumina. We continue to develop applications for 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 2021, we joined collaborations to facilitate rapid advancements in building a broader application base for QIAcuity including a partnership with GT Molecular to provide a SARS-CoV-2 wastewater testing workflow, with Atila BioSystems to advance digital PCR in non-invasive prenatal testing, and with Actome to develop protein analysis solutions.

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 continue to drive the growth of our digital marketing channels - including our website (www.qiagen.com), product-specific sites and social media. Since the onset of the pandemic there has been an increase in virtual events and use of digital sales channels. We have likewise increased the activities in digital marketing to adapt to these market changes, such as installing an in-house studio to facilitate creation of video content and live virtual events.

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 2021, 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, 2021, we owned 338 issued patents in the United States, 273 issued patents in Germany and 1,832 issued patents in other major industrialized countries. We had 425 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 below 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, including those relating to device safety and efficacy, set out in an annex of the Directive. According to the IVD Directive, EU Member States presume compliance with these essential requirements for devices that are in conformity with the relevant national standards transposing the harmonized standards, such as ISO 13485:2016, the quality system 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 EU declaration of conformity procedure to obtain a CE marking.

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, 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), IVD devices 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 May 25, 2024 under some conditions including fulfillment of specific requirements in the IVDR, but ultimately most products will have to be approved. Under the Directive the majority of QIAGEN products were under the self-declaration classification, while under IVDR most 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, the IVDR imposes additional requirements relating to post-market surveillance and submission of post-market performance follow-up reports. On January 25, 2022, Regulation (EU) 2022/112 was published to extend the transitional provisions of IVDR (EU) 2017/746, allowing most devices with their EC Declaration of Conformity under the IVD Directive to be placed on the market and/or put into service for an additional timeframe of 3-6 years depending on their appropriate risk class under the IVDR.

The EC has designated six (6) Notified Bodies to perform conformity assessments under the IVDR, including QIAGEN's Notified Body, TÜV Rheinland. MedTech Europe has issued guidance relating to the IVDR 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. With respect to the current COVID-19 pandemic, the EC has classified SARS-CoV-2 assays as high risk.

The General Data Protection Regulation (GDPR) of the European Union, imposes 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. GDPR and other EU data privacy and security 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, fines, 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.

United Kingdom Regulations

The UK's withdrawal from the EU has major ramifications for IVD manufacturers. Among other things, companies now have to follow new procedures that 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 guidance on how the country will regulate IVDs after January 1, 2021. According to MHRA, IVDs 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, although companies wishing to place IVDs on the UK market are required to register as such with MHRA. After July 1, 2023, companies selling in the UK will have to obtain a new marking called a UK Conformity Assessed mark (UKCA).

United States 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.

Certain types of tests, like some that we manufacture and sell for research use only in the United States, are not subject to the 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 IVDs that are designed, manufactured and used within a single accredited, clinical laboratory, have generally been subject to enforcement discretion and not actively regulated by the FDA. As LDTs have increased in complexity, the FDA has taken steps towards developing a risk-based approach to the regulation of LDTs; however, most LDTs remain under FDA enforcement discretion. 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, and it was reintroduced in substantially unchanged form in June 2021. If enacted, clinical laboratories that develop and offer LDTs and traditional IVD medical device manufacturers would be subject to similar 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.

Medical devices are classified into one of three classes depending on the controls deemed by the FDA to be necessary to reasonably assure their safety and effectiveness. Class I devices are generally exempt from premarket review and are subject to general controls, including labeling requirements, and adherence to the FDA's Quality System Regulations (QSR), which are device-specific current good manufacturing practices. Class II devices are generally subject to premarket notification (or 510(k) clearance), the QSR, general controls and special controls, including performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to premarket approval (PMA). The payment of a user fee, which is typically adjusted annually, to the FDA is usually required upon filing a premarket submission (e.g., premarket notification, premarket approval, or De Novo classification request) for FDA review.

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 is not subject to premarket approval. A device is substantially equivalent to a predicate device if its intended use(s), performance, safety and technological characteristics are similar to those of the predicate; or has a similar 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 determines that the device (1) is not substantially equivalent to a predicate device, (2) has a new intended use compared to the identified predicate, (3) has different technological characteristics that raise different questions of safety and effectiveness, or (4) has new indications for use or technological characteristics and required performance data were not provided, it will issue a "Not Substantially Equivalent" (NSE) determination. If the FDA determines that the applicant's device is substantially equivalent to the identified predicate device(s), the agency will issue a 510(k) clearance letter that authorizes commercial marketing of the device for one or more specific indications for use.

De Novo Classification. If a previously unclassified new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. However, if such a device would be considered low or moderate risk (in other words, it does not rise to the level of requiring the approval of a PMA), it may be eligible for the De Novo classification process. The De Novo classification process allows a device developer to request that the novel medical device be reclassified as either a Class I or Class II device, rather than having it regulated as a high risk Class III device subject to the PMA requirements. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device.

In October 2021, FDA issued a final rule that would formally codify requirements for the medical device De Novo process and the procedures and criteria for product developers to file a De Novo classification request (86 Fed. Reg. 54,826). Although the final rule does not affect marketed products, and likely not expected to impact products in current development, the FDA's goals in promulgating the final rule are to create a predictable, consistent, and transparent De Novo classification process for innovative medical device developers.

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. A clinical trial involving a "significant risk" device may not begin until the sponsor submits an investigational device exemption (IDE) application 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 and begin the substantive review process. 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 manufactured and sold by us pursuant to FDA clearances or approvals will be subject to pervasive and continuing regulation by the FDA, including quality system requirements, 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 Secretary of the U.S. Department of Health and Human Services declared a public health emergency and authorized the FDA to issue emergency use authorizations (EUAs) to provide more timely access to critical medical countermeasures (including medicines and diagnostic tests) when there are no adequate, approved, and available alternative options. EUAs remain in effect until the emergency declaration ends unless the FDA decides to revise or revoke an EUA at an earlier point as the agency considers public health needs during the emergency and new data on an authorized product's safety and effectiveness, or as products meet the criteria for FDA approval or clearance. Manufacturers of several types of SARS-CoV-2 assays have been granted EUAs, including QIAGEN. The FDA has indicated the withdrawal of EUAs for COVID-19 countermeasures will be done in a gradual, phased process and issued draft guidance on a transitional plan.

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

The FDA indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion diagnostic devices, as it does with all medical devices. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the IVD companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness. 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.

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." RUO refers to devices that are in the laboratory phase of development, while 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 pursuant to long-standing FDA guidance on RUO/IUO diagnostics. 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 may then develop, validate and promote for clinical use. However, QIAGEN does not promote these products for use in LDTs or assist in the development of the LDTs for clinical diagnostic use.

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 health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically (Covered Entities,), as well as individuals or entities that perform services for them involving the use, or disclosure of, individually identifiable health information or "protected health information" under HIPAA. Such service providers are called "Business Associates." 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 to maintain the security of protected health information.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act (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 and Business Associates.

Under 'HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured. 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.

Our Redwood City entity serves in some cases as a Business Associate to customers who are subject to the HIPAA regulations. In this capacity, we 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.

California has also adopted the California Consumer Privacy Act of 2018, or CCPA, which took effect on January 1, 2020 and became enforceable by the state attorney general on July 1, 2020. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

The regulations issued under the CCPA have been modified several times. Additionally, a new privacy law, the California Privacy Rights Act, or CPRA, was approved by California voters in the election on November 3, 2020. The CPRA will modify the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses stemming from efforts to comply, and additional potential for harm and liability for failure to comply. Other states in the U.S. are considering privacy laws similar to the CCPA. In February 2021, the Virginia legislature became the second to enact a state-specific law called the Consumer Data Protection Act, or CDPA, which includes key differences from California's law, further complicating compliance by industry and other stakeholders.

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.

U.S. Fraud and Abuse Laws and Other Healthcare Regulations

A variety of state and federal laws prohibit fraud and abuse involving state and federal healthcare programs, as well as commercial insurers. These laws are interpreted broadly and enforced aggressively by various federal and state agencies, including the Centers for Medicare & Medicaid Services (CMS), the Department of Justice (DOJ), and the Office of Inspector General for the U.S. Department of Health and Human Services (OIG). The Company seeks to conduct its business in compliance with all applicable federal and state laws.

State and federal fraud and abuse laws may be interpreted and applied differently, and arrangements and business practices could be subject to scrutiny under them by federal or state enforcement agencies. Sanctions for violations of these laws could result in a wide range of penalties, including but not limited to significant criminal sanctions, civil fines and penalties.

The Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) prohibits, in pertinent part, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce that person:

- To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made by federal healthcare programs; or
- To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made by a federal healthcare program.

A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. Recognizing that the AKS is broad and potentially applies to innocuous or beneficial arrangements, the OIG issued regulations, commonly known as "safe harbors," which set forth certain requirements that, if fully met, insulate a given arrangement or conduct from prosecution under the AKS. The AKS also has statutory exceptions that provide protection similar to that of safe harbors. If, however, an arrangement does not meet every requirement of an exception or safe harbor, the arrangement does not necessarily violate the AKS. A facts-and-circumstances analysis is necessary to determine AKS compliance or lack thereof. The statutory penalties for violating the AKS include imprisonment and criminal fines. In addition, through application of other laws, conduct that violates the AKS can give rise to civil monetary penalties and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Claims including items or services resulting from a violation of the AKS also constitute a false or fraudulent claim for purposes of the False Claims Act.

In addition to the federal AKS, many states have their own anti-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 to both state healthcare programs and commercial insurers. The penalties for violating state anti-kickback provisions can be severe, including criminal and civil penalties (including penalties under the state false claims law), imprisonment, and exclusion from state healthcare programs.

The False Claims Act

The federal False Claims Act (FCA) imposes civil liability on any person or entity that, among other things, knowingly presents, or causes to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly makes, uses or causes to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay money to the federal government. The FCA also prohibits the knowing retention of overpayments (sometimes referred to as "reverse false claims").

In addition, the FCA permits a private individual acting as a "whistleblower" (also referred to as a "relator") to bring FCA actions on behalf of the federal government under the statute's qui tam provisions, and to share in any monetary recovery. The federal government may elect or decline to intervene in such matters, but if the government declines intervention, the whistleblower may still proceed with the litigation on the government's behalf.

Penalties for violating the FCA include payment of up to three times the actual damages sustained by the government, plus substantial per-claim statutory penalties, as well as possible exclusion from federal healthcare programs.

Various states have enacted similar laws modeled after the FCA that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to any payor, including commercial insurers.

There is also a federal criminal false claims statute that prohibits, in pertinent part, the making or presentation of a false claim, knowing such claim to be false, to any person or officer in the civil, military, or naval service or any department or agency thereof. Potential penalties for violating this statute include fines or imprisonment.

Health Care Fraud and False Statements

The federal healthcare fraud statute criminalizes knowingly and willfully defrauding a healthcare benefit program, which includes including commercial insurers. A violation of this statute may result in fines, imprisonment, or exclusion from federal healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute may result in fines or imprisonment.

Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law (CMP Law) prohibits, among other things, (1) the offering or transfer of remuneration to a beneficiary of Medicare or a state healthcare program if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal healthcare program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. The penalties for violating the CMP Law include exclusion from federal healthcare programs, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

Physician Payments Sunshine Act

The federal Physician Payments Sunshine Act (Sunshine Act) imposes reporting requirements on manufacturers of certain devices, drugs, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP), with certain exceptions. Manufacturers to which the Sunshine Act applies must collect and report annually certain data on certain payments and transfers of value by them (and in some cases their distributors) to physicians, teaching hospitals, and certain advanced non-physician healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members. For reporting beginning January 1, 2022, U.S.-licensed physician assistants, clinical nurse specialists, certified nurse-midwives, certified nurse anesthetists, and nurse practitioners must be included in the provider types subject to Sunshine Act reporting. The report program (known as the Open Payments program) is administered by CMS.

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.

Failure to comply with the Sunshine Act or state equivalents could result in civil monetary penalties, among other sanctions, depending upon the nature of the violation.

Despite extensive procedures to ensure compliance, we may also be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (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.

Rest of the World Regulation

In addition to regulations in the United States and the EU, we are subject to a variety of regulations governing clinical studies and commercial sales and distribution of molecular testing instruments, consumables and digital solutions in other jurisdictions around the world. These laws and regulations typically require the licensing of manufacturing facilities, as well as controlled research, testing and governmental authorization of product candidates. Additionally, they may require adherence to good manufacturing, clinical and laboratory practices.

We must obtain approval from regulatory authorities in all countries where we distribute our products. The requirements governing the conduct of product authorization, pricing and reimbursement vary greatly from country to country. If we fail to comply with applicable regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, or criminal prosecution.

Reimbursement

United States

In the United States, payments for diagnostic tests come from several sources, including commercial insurers, (which might include health maintenance organizations and preferred provider organizations); government healthcare programs (such as Medicare or Medicaid); and, in many 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.

For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. The suspension was subsequently extended through March 31, 2022, with a reduction of the suspension to 1% sequester through June 30, 2022.

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 (CPT) code used to identify a test. The American Medical Association (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 Healthcare Common Procedure Coding System (HCPCS) codes for medical billing and reimbursement purposes. Level I HCPCS codes are comprised of current CPT codes, while Level II HCPCS codes primarily represent non-physician services and Level III HCPCS codes are local codes developed by Medicaid agencies, Medicare contractors and commercial 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 a 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 commercial insurers and government 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 HCPCS 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), applicable laboratories are required to report to CMS commercial insurer payment rates and volumes for their tests. CMS uses the data reported and the HCPCS code associated with the test to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for certain clinical diagnostic laboratory tests (CDLTs), subject to certain phase-in limits. For a CDLT that is assigned a new or substantially revised CPT code, the initial payment rate is assigned using the gap-fill methodology.

If the test at issue falls into the category of new advanced diagnostic laboratory test (ADLT) instead of CDLT, the test will be paid based on an actual list charge for an initial period of three quarters, before being shifted to the weighted median commercial insurer rate reported by the laboratory performing the ADLT. Laboratories offering ADLTs are subject to recoupment if the actual list charge exceeds the weighted median private payor rate by a certain amount.

On December 20, 2019, the President signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act (LAB Act). The LAB Act delayed until the first quarter of 2021 the reporting of payment data under PAMA for CDLTs that are not ADLTs. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which Congress passed in March 2020, again delayed reporting by an additional year, until the first quarter of 2022. The CARES Act also delayed the next PAMA reporting period for CDLTs to January 1, 2022 through March 31, 2022. Then, on December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included a provision that further delays the next PAMA reporting period for CDLTs that are not ADLTs to January 1, 2023 through March 31, 2023. New CLFS rates for CDLTs will thus be established based on that data beginning in 2024, subject to phase-in limits.

CMS's methodology under PAMA (as well as the willingness of commercial insurers to recognize the value of diagnostic testing and pay for that testing accordingly) renders commercial insurer payment levels even more significant. This calculation methodology has resulted in significant reductions in reimbursement, even though CMS imposed caps on those reductions. Given the many uncertainties built into PAMA's price-setting process, it is difficult to predict how payments made by CMS under the CLFS may change from year to year.

Coverage Decisions: When deciding whether to cover a particular diagnostic test, 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. Commercial insurers and government payors have separate processes for making coverage determinations, and commercial insurer 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, commercial insurers 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.

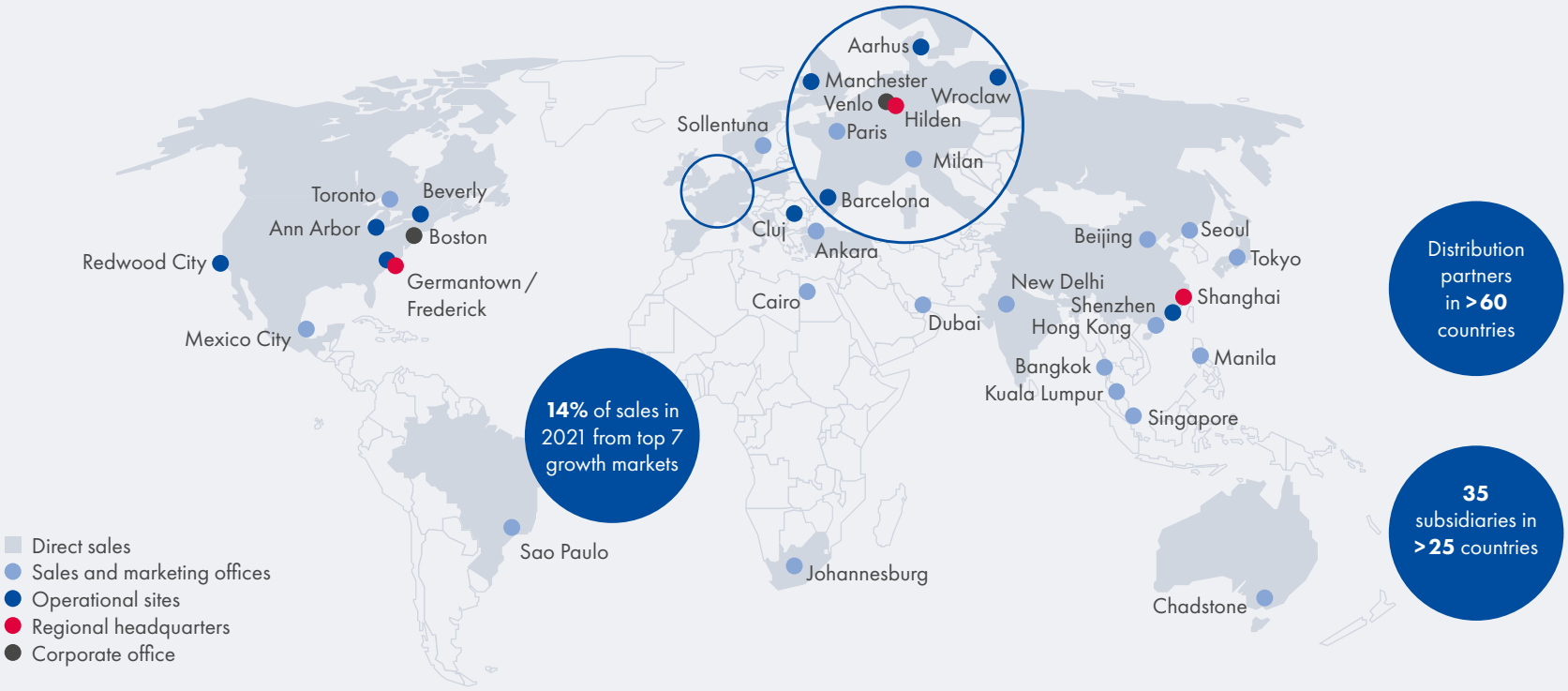
European Union

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 the Financial Results section to this Annual Report.

Our global presence: Focus on the most attractive developed and emerging markets



Description of Property

Our primary production and manufacturing facilities for consumable products are located in Germany, the United States, Spain 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 $189.9 million, $132.8 million and $118.0 million for 2021, 2020 and 2019, 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 facilities that accommodate cGMP production, special areas were built and 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: 2015, ISO 13485:2016, MDSAP. 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 corporate headquarters are located in leased office space in Venlo, The Netherlands. The below table summarizes our material facilities. Other subsidiaries throughout the world lease smaller amounts of space.

Location	Country	Purpose	Owned or Leased	Square feet
Hilden	Germany	Manufacturing, warehousing, distribution, research and administration	Owned	786,000
Germantown, Maryland	USA	Manufacturing, warehousing, distribution and administration	Owned	285,000
Shenzhen	China	Research, manufacturing, warehousing, distribution, and administration	Leased	102,150
Manchester	UK	Research and Service Solutions	Leased	96,300
Ann Arbor, Michigan	USA	Manufacturing, warehousing, distribution, and administration	Leased	81,000
Wroclaw	Poland	Shared service center	Leased	65,100
Beverly, Massachusetts	USA	Enzyme manufacturing	Leased	44,000
Frederick, Maryland	USA	Manufacturing, warehousing, distribution and research	Leased	42,000
Barcelona	Spain	Research, manufacturing, warehousing, distribution, and administration	Leased	31,900
Manila	Philippines	Shared service center	Leased	29,300
Ann Arbor, Michigan	USA	Service Solutions, warehousing and administration	Leased	28,000
Minden, Nevada	USA	Service Solutions	Leased	19,000
Germantown, Maryland	USA	Service Solutions and training center	Leased	13,500
Redwood City, California	USA	Bioinformatics	Leased	12,700

In 2021 and 2020, we made investments to expand production lines in Germany, Spain and the U.S. to meet both current demand as well as future growth. At each of our owned facilities in Hilden, Germany and Germantown, Maryland, there is room for future expansion of up to 300,000 square feet of facility space.

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.

Risks Management

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 the opportunity to successfully implement mitigation actions on a timely basis. 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 outlines the responsibilities of our Managing Board and Supervisory Board 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 internal controls 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 global economic risks, and currency rate fluctuations • Evaluating and monitoring international hostilities • Monitoring financial reporting risks, including multi-jurisdiction tax compliance • Reviewing possible asset impairment events • Assessing cyber security, 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 a new product 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 and sales. 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.

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 the QIAsymphony, QIAstat-Dx, NeuMoDx and QIAcuity systems could significantly affect sales of consumables 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 $2.25 billion in 2021 from $1.42 billion in 2017. We have made a series of acquisitions in recent years, including the acquisitions of NeuMoDx Molecular, Inc. in 2020, assets from Formulatrix, Inc. in 2019 for our entry into digital PCR with QIAcuity, and N-of-One in January 2019 to strengthen our position in bioinformatics. 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 and realize 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 potentially 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 initially 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. We may experience an adverse impact on our results of operations due to the current geopolitical tensions caused by the Russian invasion of Ukraine. The governments of the European Union, the United States, Japan and other jurisdictions have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the levels of government spending or the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets.

Further, the global economy recovery from the COVID-19 pandemic will depend on many factors, including the recovery of the supply chain. In the near term we anticipate continued exposures on the supply chain and we have inventory agreements with the majority of our suppliers and we closely monitor stock levels to maintain adequate supplies. In 2021, we have been able to secure a stable supply of chemicals, bioreagents, plastics and packaging materials with only moderate price adjustments. However

in electronics, we have seen shortages that needed to be mitigated with long term contacts and high volume agreements, which at times included price increases. These increases are considered in the pricing of our products. We strive to maintain inventories at a sufficient level to ensure reasonable customer service levels, to guard against normal volatility in availability and we continue to work to circumvent shortages and keep pricing competitive. However, 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 central banks in the U.S., the UK and the Euro Zone have started to signal a revision of the very accommodating monetary policies. Combined with the high degree of uncertainty in the global financial markets and the economic conditions generally and as a result of the war in Ukraine, this may impact our future performance. 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 action 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, epidemics or pandemics, 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., Spain 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, or other natural events which may be associated with climate change. 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.

Terrorist attacks and international hostilities and instability in any region could adversely affect our business.

Terrorist attacks, the outbreak of war, or the existence of international hostilities could damage the world economy, adversely affect the global supply chain and adversely affect both our ability to sell our products to certain regions or purchase supplies from such regions. In particular, the warfare, political turmoil or terrorist attacks in Ukraine could adversely impact our financial condition, result of operations and cash flows. In February 2022, Russian troops invaded Ukraine. Although the severity and duration of the ongoing military action are highly unpredictable, the conflict in Ukraine could materially disrupt our operations in Europe and/or increase their costs. In addition, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions being levied by the European Union, the United States and other countries against Russia, with additional potential sanctions threatened and/or proposed. Russia's military incursion and the resulting sanctions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as, potentially, the price of our common shares. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions caused by Russian military action or resulting sanctions may magnify the impact of other risks described in this Annual Report.

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 quantity or quality to produce certain products, and this could have an adverse impact on our results of operations.

The ongoing COVID-19 pandemic has resulted in increased global supply chain constraints and disruption to the operations of certain of our suppliers, and we cannot predict the duration or severity of current supply chain issues, including increased freight costs. Supply chain constraints have required, and may continue to require, in certain instances, alternative delivery arrangements and increased costs and could have a material adverse effect on our business and 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, par value EUR 0.01 per share (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 and 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 updating 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 of data or other operational disruption. Failures in 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. Furthermore, there is an increased risk of cyber security attacks by state actors due to the current conflict between Russia and Ukraine. Recently, Russian ransomware gangs have threatened to increase hacking activity against critical infrastructure of any nation or organization that retaliates against Moscow for its invasion of Ukraine. Any such increase in such attacks on our third-party providers or other systems could adversely affect our network systems or other operations. 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 (the CCPA), 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. Virginia and Colorado also enacted comprehensive data privacy laws similar to the CCPA, both of which will be effective in 2023. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. 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.

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

Changes in the market 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.

We sell our products to 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 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 U.S. Food and Drug Administration (FDA) or similar non-U.S. authorities. Our competitors' development of alternative products offering superior technology, greater cost-effectiveness and/or receiving 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 debate 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 preclinical 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 in vitro diagnostic medical devices (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 growth markets, which exposes us to risks.

Our top seven growth markets are Brazil, China, India, South Korea, Mexico, Russia and Turkey, which together accounted in 2021 for approximately 14% of total sales. 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 the case of Russia, which represented less than 1.0% of consolidated net sales in 2021, our expansion could be limited due to the economic fallout of the recent and ongoing Russian invasion of Ukraine, which has led to widespread economic sanctions on Russia and the devaluation of the Russian ruble. 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.

Sales practices may change 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, 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 in the future for us to obtain financing 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 London Interbank Offered Rate (LIBOR) has historically been widely used as a reference for setting the interest rate on loans globally. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform or discontinuation. In particular, on July 27, 2017, the Chief Executive of the U.K. Financial Conduct Authority, which regulates LIBOR, announced that it will no longer persuade or compel banks to submit rates for the calculation of LIBOR after 2021. Subsequently, the ICE Benchmark Administration announced its plan to extend the date most U.S. dollar LIBOR values would cease being computed to June 30, 2023. Following the end of 2021, LIBOR ceased being a widely used benchmark interest rate. Presently, we do hold debt and derivative instruments that use LIBOR. While we expect to settle these instruments in October 2022 and certain agreements do contain language for the determination of interest rates in the event the LIBOR rate is not available, if changes to these agreements are required, 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, 2021, we had outstanding long-term debt of $1.9 billion, of which $847.6 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 Annual 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, 2021, our consolidated balance sheet reflected $2.4 billion of goodwill and $627.4 million of intangible assets. Goodwill is recorded when the purchase price of a business exceeds the fair value of the tangible and separately measurable intangible net assets. U.S. generally accepted accounting principles (U.S. GAAP) require us to test goodwill for impairment on an annual basis or when events or circumstances occur indicating that goodwill might be impaired. Long-lived assets, such as intangible assets with finite useful lives, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment review often cannot be done at the level of the individual asset and it must instead be applied to a group of assets. For the purpose of our annual goodwill impairment testing based on the current circumstances of how we manage our business, this group of assets is the Company as a whole. If we determine that any of our goodwill or intangible assets were impaired, we will be required to take an immediate charge to earnings and our results of operations could be adversely affected.

Our strategic equity investments may result in losses.

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

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

Doing business internationally creates certain risks.

Our business involves operations in several countries outside of the U.S. Our consumable manufacturing facilities are located in Germany, China, Spain 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. Further, any misuse or other wrongful use of our products could expose us to negative publicity resulting in reputation or brand damage with customers or partners. 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.

Real or perceived defects in or misuse of our products could adversely affect our results of operations, growth prospects and reputation.

We currently market our products in 130 countries. Due to the size and breadth of our operations, we may not always be able to track the use of our products by the end users. If our products are misused or are perceived to be misused, this could adversely affect our reputation and our customers' willingness to buy from us, and adversely affect market acceptance or perception of our products.

Many of our customers, especially those in law enforcement and government who use our products for forensic testing, human identification, food testing or other purposes, use our products in applications that are of public interest or critical to their businesses or missions and may thus have a lower risk tolerance to defects in our products than

to defects in other, less critical, products. A defect in or misuse of any of our products by our law enforcement customers could lead to interference with the administration of justice, for example by corrupting forensic evidence. Any defects or misuse, real or perceived, cause us to lose sales opportunities, increase our service costs, incur replacement costs, lose customers or subject us to liability for damages and divert our resources from other tasks, any one of which could materially and adversely affect our business, results of operations and financial condition. In addition, our products could be perceived as ineffective for reasons outside of our control.

Additionally, if any of our customers, government or otherwise, use or are perceived to use our products in a manner that is unethical, unlawful or inconsistent with our values, this may damage our reputation and results of operations. We strive to ensure that our products are used only in ethical and lawful ways, but we cannot provide any assurance that we will not be subject to claims from third parties alleging that our products were misused. Any allegations of misuse by our customers or third parties may damage our reputation, even if we took no part in the misuse or take immediate action to sever ties with such customers.

We believe that our brand and reputation are critical to driving our business. Building our brand will depend largely on our ability to continue to provide top-tier service, including high quality products at appropriate price points, which we may not do successfully. Negative reviews or publicity about our products or business, especially on media outlets, could harm our reputation and diminish our ability to make additional sales, which would adversely affect our business, financial condition, and results of operations.

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

Our success depends to a large extent on our ability to develop proprietary products and technologies and to establish and protect our patent and trademark rights in these products and technologies. As of December 31, 2021, we owned 338 issued patents in the United States, 273 issued patents in Germany and 1,832 issued patents in other major industrialized countries. In addition, as of December 31, 2021, we had 425 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 $59.00 to a low of $32.97. On the Frankfurt Stock Exchange our Common Shares have ranged from a high of €51.56 to a low of €29.55 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, 2021, a total of approximately 227.1 million Common Shares were outstanding along with approximately 4.0 million additional shares reserved for issuance upon exercise or release of outstanding stock options and awards, of which 18.0 thousand were vested. A total of approximately 12.9 million Common Shares are reserved and available for issuances under our stock plans as of December 31, 2021, 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, 2021, 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.

Critical Accounting Policies, Judgments and Estimates

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

Revenue Recognition

We recognize revenue when control of promised goods or services is transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation requires management's judgments and estimates. Sales arrangements which require a measure of progress toward completion by measuring actual hours incurred to date as a proportion of the total budgeted hours of the project also involves management's judgments and estimates. While the majority of our sales agreements contain standard terms and conditions, we do enter into agreements that contain multiple products or services or non-standard terms and conditions. Sometimes it is difficult to determine whether there is more than one performance obligation under a sales agreement and if so, how and when revenue should be recognized is subject to certain estimates or assumptions. Should our judgments and estimates not be correct, revenue recognized for any reporting period could be adversely affected.

Income Taxes

Calculation of our tax provision is complex due to our international operations and the multiple taxing jurisdictions in which we operate. Some of our deferred tax assets relate to net operating losses (NOL). The utilization of NOLs is not assured and is dependent on generating sufficient taxable income in the future. Although management believes it is more likely than not that we will generate sufficient taxable income to utilize substantially all NOL carryforwards, evaluating the NOLs related to our newer subsidiaries requires us to make estimates that we believe are reasonable, but may also be highly uncertain given that we do not have direct experience with these subsidiaries or their products. Thus, the estimates may be subject to significant changes from period to period as we gain that experience. To the extent that our estimates of future taxable income are insufficient to utilize all available NOLs, a valuation allowance will be recorded in the provision for income taxes in the period the determination is made, and the deferred tax assets will be reduced by this amount, which could be material. In the event that actual circumstances differ from management's estimates, or to the extent that these estimates are adjusted in the future, any changes to the valuation allowance could materially impact our financial position and results of operations.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in many jurisdictions across our global operations. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes on the basis of technical merits. We record unrecognized tax positions in accordance with ASC 740 and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which the new information is available.

Investments

Generally accepted accounting principles require different methods of accounting for an investment depending on the level of influence that we exert. Assessing the level of influence involves subjective judgments. If management's assumptions with respect to its level of influence differ in future periods and we therefore have to account for these investments under a method other than the cost method, it could have a material impact to our financial statements.

We have equity investments accounted for under the measurement alternative as these equity securities do not have readily determinable fair values and are not accounted for under the equity method. This measurement alternative requires these investments to be measured at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. At each reporting date, we review each investment for impairment, considering factors such as book values from the most recent financial statements, and forecasts and expectations of the investee, and also for any observable price changes from stock transactions of the issuer. If an impairment is determined to have occurred, estimation of the fair value of these non-marketable equity investments is inherently subjective. Therefore, in the case of an impairment or an observable price change occurs, it could require a write-down or write-up of the investment that could materially impact our financial position and results of operations.

Additionally, we have made strategic investments in certain companies as more fully described in Note 10 "Investments" to the Consolidated Financial Statements, some of which are variable interest entities. FASB ASC Topic 810 requires a company to consolidate a variable interest entity in which it holds a variable interest if it is designated as the primary beneficiary of that entity even if the company does not have a majority of voting interests. A variable interest entity is generally defined as an entity with insufficient equity to finance its activities or where the owners of the entity lack the risk and rewards of ownership. Assessing the requirements of ASC Topic 810 involves subjective judgments. If management's assumptions with respect to the criteria differ in future periods, and we therefore have to account for these investments under a different method, it could have a material impact on our financial statements.

Amortized Intangible Assets

We assess amortized intangible assets at least annually, as of October 1st of each year, for indications of impairment. Intangibles are assessed for recoverability considering the contract life, where applicable, and the period of time over which the intangible will contribute to future cash flow. The unamortized cost of intangible assets, where cash flows are independent and identifiable from other assets, is evaluated periodically and adjusted, if necessary, if events and circumstances indicate that a decline in value below the carrying amount has occurred. Due to the numerous variables associated with our judgments and assumptions and the effects of changes in circumstances affecting the valuation, both the precision and reliability of the resulting estimates are subject to uncertainty. As additional information becomes known, we may change our estimates.

Acquisitions

We frequently enter into business combinations and must determine whether an acquired entity is considered to be a business or an asset or group of assets under ASU 2017-01, *Business Combinations: Clarifying the Definition of a Business*. A portion of the purchase price can only be allocated to goodwill in a business combination. Transaction costs are expensed in a business combination yet capitalized in an asset acquisition. Contingent payments and in-process research and development costs are also handled differently. A set of assets is not a business if substantially all of the fair value of the acquired gross assets is concentrated in a single asset or group of similar identifiable assets. In determining whether an acquired entity is considered to be a business or a set of assets, application of the "substantially all" threshold requires judgment.

The purchase price allocation for acquisitions of a business requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. An acquisition may include contingent consideration as part of the purchase price. Contingent consideration is accounted for at fair value at the acquisition date with subsequent changes to the fair value being recognized in earnings.

We have made several acquisitions of businesses in recent years. The purchase prices for the acquisitions were allocated to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition dates. In most acquisitions, we engage an independent third-party valuation firm to assist us in determining the estimated fair values of acquired in-process research and development and identifiable intangible assets. Such a valuation requires significant estimates and assumptions, including but not limited to determining the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, estimating projected revenue and related growth rates, estimating future cash flows, estimating customer attrition rates and developing appropriate discount rates. We believe the estimated fair values of contingent consideration and assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocations may change during the allowable allocation period, which is up to one year from the acquisition dates, if additional information becomes available.

Fair Value Measurements

We have categorized our assets and liabilities that are measured at fair value, based on the priority of the inputs to the valuation techniques, in a three-level fair value hierarchy: Level 1 - using quoted prices in active markets for identical assets or liabilities; Level 2 - using observable inputs other than quoted prices; and Level 3 – using unobservable inputs. We primarily apply the market approach for recurring fair value measurements, maximize our use of observable inputs and minimize our use of unobservable inputs. We utilize the mid-point price between bid and ask prices for valuing the majority of our assets and liabilities measured and reported at fair value. In addition to using market data, we make assumptions in valuing assets and liabilities, including assumptions about risk and the risks inherent in the inputs to the valuation technique.

Certain of our derivative instruments, which are classified in Level 2 of the fair value hierarchy, are valued using industry-standard models that consider various inputs, including time value, volatility factors, and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these inputs are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable prices at which transactions are executed in the marketplace.

Certain of our acquisitions involve contingent consideration, the payment of which is contingent on the occurrence of future events. Contingent consideration is classified in Level 3 of the fair value hierarchy and is initially recognized at fair value as a cost of the acquisition. After the acquisition, the contingent consideration liability is remeasured each reporting period. The fair value of contingent consideration is measured predominantly on unobservable inputs such as assumptions about the likelihood of achieving specified milestone criteria, projections of future financial performance, assumed discount rates and assumed weightings applied to potential scenarios in deriving a probability weighted fair value. Significant judgment is used in developing these estimates and assumptions both at the acquisition date and in subsequent periods. If actual events differ from management's estimates, or to the extent these estimates are adjusted in the future, our financial condition or results of operations could be affected in the period of any change.

Additionally, our Level 3 instruments include non-marketable equity security investments. Under the measurement alternative, the carrying value is measured at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. Adjustments are determined primarily based on a market approach as of the transaction date.

For other fair value measurements, we generally use an income approach to measure fair value when there is not a market observable price for an identical or similar asset or liability. This approach utilizes management’s best assumptions regarding expectations of projected cash flows, and discounts the expected cash flows using a commensurate risk-adjusted discount rate.

The above listing is not intended to be a comprehensive list of all our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles in the United States, with limited or no need for management's judgment. There are also areas in which management's judgment in selecting available alternatives may or may not produce a materially different result. See our audited consolidated financial statements and notes thereto in the Financial Results section of this Annual Report, containing a description of accounting policies and other disclosures required by generally accepted accounting principles in the United States.

Recent Authoritative Pronouncements

For information on recent accounting pronouncements impacting our business see Note 2 "Effects of New Accounting Pronouncements" of the Notes to Consolidated Financial Statements included in the Financial Results section of this Annual Report.

Performance Review

Our future operating results may be affected by various risk factors, many of which are beyond our control.

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

Operating Results

Delivering on our promises: 2021 accomplishments

Empowered teams achieved our goals
- FY 2021: +19% CER sales growth, Adj EPS $2.63 CER, free cash flow $449 million
- Set ambitious but realistic targets: Met or beat our non-COVID sales expectations for 10 consecutive quarters

Focused on five pillars of growth
- ~65% of R&D investments into five pillars of growth
- Launched >10 assays and 3 new instruments

Increased transparency and candor
- Established new revenue reporting in product groups
- De-risked outlook by removing COVID-19 volatility

Advanced our ESG initiatives
- Set commitment to be carbon neutral by 2050
- Ensured effective governance with two new Supervisory Board members

Sample technologies
- QIApre&Amp for high-throughput COVID testing
- EZ2 Connect instruments

QuantiFERON
- QFT SARS-CoV-2 T cell test (CE-IVD)
- QIAreach QFT-TB (CE-IVD)
- QFT-Lyme test on DiaSorin (CE-IVD)
- QFT-TB Gold Plus on DiaSorin XS (FDA)

QIAstat-Dx
- Respiratory 4-plex assay (RSV, Influenza A/B, COVID-19)
- QIAstat-Dx Meningitis panel (CE-IVD registration)
- QIAstat-Dx Gastrointestinal panel (FDA submission)

NeuMoDx
- Respiratory 4-plex assay (RSV, Influenza A/B, COVID-19)
- Human adenovirus (CE-IVD)
- CMV (Cytomegalovirus) (CE-IVD)

QIAcuity digital PCR
- Wastewater testing solution for COVID-19 surveillance

Overview

In 2021 QIAGEN exceeded two billion dollars in total net sales for the first time in the company's history due to strong performance of our non-COVID product portfolio and our continued support of the global response to the pandemic through testing solutions for COVID-19. Strong sales in 2021 supported profitability and cash flow while we continued to make investments to strengthen our portfolio, in particular the five pillars of growth which consist of sample technologies, the digital PCR (Polymerase Chain Reaction) 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 are moving ahead with large manufacturing upscaling projects and investing in research and development for menu expansion of our key platforms. These investments are designed to enable us to transition our installed base of instruments and systems into new applications while supporting the global response to COVID-19 testing.

Financial highlights of 2021 include:

- Net sales grew 20% in 2021 driven by growth of 24% in our non-COVID product portfolio demonstrating that we have a robust portfolio anchored by our five pillars of growth to drive strong business expansion beyond the pandemic. Net sales of our COVID-19 products grew 14% as we continue to support the global response to the COVID-19 pandemic. 2021 results include NeuMoDx Molecular Inc. (NeuMoDx) which we acquired in September 2020. For additional information on this acquisition see Note 5 "Acquisitions."
- Operating income margin rose to 28.0% in 2021 from 20.7% in 2020 primarily due to lower restructuring, acquisition, integration and other expenses. Additionally, we realized efficiencies in sales and marketing as well as general and administrative expenses which more than offset the investments made to our portfolio that resulted in a reduction in gross margin and higher research and development as a percentage of sales during 2021.
- Net income rose at a slower pace than operating income due primarily to lower gains in other income, net in 2021 compared to 2020 related to the Invitae shares received and sold in connection with the sale of ArcherDX. In addition to the impacts from the change in net income, diluted EPS was also impacted by a lower number of weighted-average common shares outstanding used in calculating diluted EPS in 2021 compared to the prior year.
- Net cash provided by operating activities reflected the strong growth in net sales in 2021. Purchases of property, plant and equipment rose compared to 2020 primarily due to investments made to expand consumables production capacity for key growth products at sites in Europe and the United States.

Year Ended December 31, 2021, Compared to 2020

Net Sales

(in millions)	2021		2020		
Product type	Net sales	% of net sales	Net sales	% of net sales	% change
Consumables and related revenues	$1,986.3	88%	$1,615.4	86%	+23%
Instruments	265.3	12%	254.9	14%	+4%
Net Sales	**$2,251.7**		**$1,870.3**		**+20%**
Customer class					
Molecular Diagnostics	$1,143.7	51%	$904.0	48%	+27%
Life Sciences	1,108.0	49%	966.4	52%	+15%
Net Sales	**$2,251.7**		**$1,870.3**		**+20%**
Non-COVID and COVID-19 products					
Non-COVID products	$1,547.2	69%	$1,252.4	67%	+24%
COVID-19 products	704.4	31%	617.9	33%	+14%
Net Sales	**$2,251.7**		**$1,870.3**		**+20%**

Consumables and related revenues showed ongoing solid trends for both non-COVID and COVID-19 related products in 2021 and grew 23% compared to 2020. Net sales of instruments grew 4% in 2021 and represented 12% of total net sales. During 2020, instruments reflected 14% of total net sales as we experienced an increase in our installed base of instruments due to the ability of these to be used in COVID-19 testing. In 2021, sales of non-COVID products grew 24% supported by improved demand trends among both Molecular Diagnostics and Life Sciences customers compared to 2020. Demand for COVID-19 test products continued through 2021 in response to the pandemic, including the rise in testing related to the Omicron variant which was identified in November 2021. Net sales were positively impacted by one percentage point from favorable currency movements against the U.S. dollar.

(in millions)	2021		2020		
Product group	Net sales	% of net sales	Net sales	% of net sales	% change
Sample technologies	$850.6	38%	$803.9	43%	+6%
Diagnostic solutions	638.8	28%	460.8	25%	+39%
PCR / Nucleic acid amplification	434.0	19%	363.6	19%	+19%
Genomics / NGS	245.1	11%	165.6	9%	+48%
Other	83.2	4%	76.6	4%	+9%
Net Sales	**$2,251.7**		**$1,870.3**		**+20%**

Sample technologies include both COVID-19 and non-COVID products involved in the first step in any molecular lab process. In 2021, non-COVID product group sales rose 14%, representing 64% of net sales for this product group on higher demand for DNA sample prep due in part to a favorable research funding environment. Sales of sample technologies for COVID-19 testing declined overall primarily due to lower sales of manual sample prep kits and instruments, while sales of automated sample prep kits, namely QIAprep&amp, were higher driven by demands for high-volume testing.

Diagnostic solutions include molecular testing platforms and products as well as Precision Medicine and companion diagnostic co-development revenues. This product group experienced growth due to improved trends in clinical testing demand in 2021. Key product drivers were the QuantiFERON latent TB test with 48% growth and 2021 sales of $281.4 million together with sales of the QIAstat-Dx syndromic testing system which grew 39% to $75 million. In the first full year following the September 2020 acquisition, NeuMoDx sales totaled $105 million in 2021, supported by demand for COVID-19 testing. Revenues from companion diagnostic co-development projects grew 25% in 2021 on the resumption of pharma research and development projects while sales of Precision Medicine companion diagnostic consumables rose 9%.

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 experienced strong demand for OEM solutions and enzymes used in third-party diagnostic kits while COVID-related sales for both consumables and instruments declined after strong demand in 2020.

Genomics / NGS includes universal NGS solutions as well as the full QIAGEN Digital Insights portfolio. Growth in this product group reflects an increased demand against weaker sales trends in 2020 due to the adverse pandemic impact on customers. As activity levels continued to rise in research and clinical applications in 2021, sales for universal consumables used in NGS in both the Life Sciences and Molecular Diagnostic applications, as well as bioinformatics revenues from QIAGEN Digital Insights, were key drivers of 2021 sales growth.

Geographic region (in millions)	**2021**	2020	% change
Americas	$1,007.4	$825.5	+22%
Europe, Middle East and Africa	814.4	682.3	+19%
Asia Pacific, Japan and Rest of World	429.9	362.6	+19%
Net Sales	**$2,251.7**	**$1,870.3**	**+20%**

Top 7 growth markets: Brazil, Russia, India, China, South Korea, Mexico and Turkey (2021: $309 million, 2020: $287 million, +8%)

The Americas led the geographic regions with 22% sales growth in 2021 due to a strong performance in the U.S. which experienced 25% growth including gains in non-COVID product group sales especially in QuantiFERON-TB and QIAcuity. Growth in the U.S. was partially offset by declines in Brazil and in Mexico compared to 2020.

The Europe, Middle East and Africa (EMEA) region was driven by growth throughout Western Europe primarily in Austria, the United Kingdom, Italy and Switzerland during 2021. EMEA was supported by two percentage points of sales growth from positive currency movements in 2021.

The Asia Pacific, Japan and Rest of World region's performance was driven by 27% growth in China compared to 2020 on improving trends in non-COVID product groups. Higher sales were also seen in Japan, Australia and South Korea, more than absorbing the decline in India compared to 2020. Sales in this region were positively impacted by three percentage points from favorable currency movements against the U.S. dollar.

Gross Profit

(in millions)	**2021**	2020	% change
Gross Profit	$1,450.8	$1,232.7	+18%
Gross Margin	64.4%	65.9%	

Gross margin between periods can be impacted by significant changes in individual product sales. The gross margin decline of 1.5 percentage points is attributable in part to changes in the consumable product mix, notably the increase in QuantiFERON latent TB test with 48% growth in 2021. Additionally, the lower gross margin reflects higher costs following our investments in expanded production capacity and higher amortization expense. Generally, our consumables and related products have a higher gross margin than our instrumentation products and service arrangements. While net sales have shifted towards a higher percentage of consumables in 2021, fluctuations in the sales levels within the product types can result in changes in gross margin between periods.

In 2021, the amortization expense on acquisition-related intangibles within cost of sales increased to $67.1 million in 2021 from $63.2 million in 2020. This net increase in amortization expense reflects the NeuMoDx intangibles acquired in 2020 partially offset by the full amortization during 2020 of assets previously acquired. Our acquisition-related intangible amortization will increase in the event of future acquisitions.

Operating Expenses

	2021		2020		
(in millions)	Expenses	% of net sales	Expenses	% of net sales	% change
Research and development	$190.0	8.4%	$149.1	8.0%	+27%
Sales and marketing	456.4	20.3%	413.7	22.1%	+10%
General and administrative	128.1	5.7%	111.7	6.0%	+15%
Acquisition-related intangible amortization	18.5	0.8%	20.8	1.1%	-11%
Restructuring, acquisition, integration and other, net	27.8	1.2%	150.0	8.0%	-81%
Long-lived asset impairments	—	—%	1.0	0.1%	-100%
Total operating expenses	$820.8	36.5%	$846.3	45.2%	
Income from operations	$630.1	28.0%	$386.4	20.7%	

Research and Development

The increase of research and development expenses as a percentage of sales as well as the overall increase in research and development is the result of the focus on our five pillars of growth, including investments in NeuMoDx, QIAstat-Dx and QIAcuity. These investments are targeting new applications within our five pillars of growth to drive sustainable post-pandemic expansion. Research and development costs for the year ended December 31, 2021, include $6.0 million of unfavorable currency exchange impact. In 2020, research and development costs reflect the suspended development of NGS-related instrument systems as discussed in Note 6 "Restructuring and Impairments". 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

The overall increase in expense reflects additional sales and marketing efforts supporting the focus on our five pillars of growth, as well as increases in freight and other supply chain costs in line with the increase in sales and includes unfavorable currency exchange impacts of $8.0 million for the year ended December 31, 2021. The increased use of digital marketing efforts during the COVID-19 pandemic was a driver in reduced sales and marketing expenses as a percentage of sales of 20.3% in 2021 compared to 22.1% in 2020. Sales and marketing expenses are primarily associated with personnel, commissions, advertising, trade shows, publications, freight

and logistics expenses, and other promotional expenses. We expect to continue building out our digital customer engagement channels and intend to closely monitor the development of sales and marketing expenses once pandemic restrictions are lifted.

General and Administrative

General and administrative expenses also decreased as a percentage of sales in 2021 compared to 2020 while overall expenses increased. General and administrative expenses include unfavorable currency exchange impacts of $1.7 million for the year ended December 31, 2021. We anticipate continued investments in cyber security and other investments in information technology systems including upgraded enterprise resource planning (ERP) systems in the coming years.

Acquisition-Related Intangible Amortization

During 2021, amortization expense on acquisition-related intangibles within operating expense decreased to $18.5 million, compared to $20.8 million in 2020. The decrease follows the full amortization of assets previously acquired in 2011. 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. Our acquisition-related intangible amortization recorded in operating expenses will increase in the event of future acquisitions.

Restructuring, Acquisition, Integration and Other, net

Restructuring, acquisition, integration and other, net expenses decreased $122.2 million in 2021 compared to the prior year. Expenses of $27.8 million during the year ended December 31, 2021 includes costs for the continued integration of NeuMoDx as well as $4.7 million jury-awarded damages to ArcherDX. We also incurred $2.4 million of charges related to the 2019 restructuring program as discussed further in Note 6.

During the year ended December 31, 2020, $150.0 million of expenses were incurred including 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.

Long-lived Asset Impairments

Impairments to property, plant and equipment during the year ended 2020 totaled $1.0 million and were incurred in connection with the 2019 restructuring measures as further discussed in Note 6 "Restructuring and Impairments."

Other Income (Expense)

(in millions)	**2021**	2020	% change
Interest income	$9.6	$10.0	-5%
Interest expense	(54.5)	(71.3)	-24%
Other income, net	40.7	114.3	-64%
Total other (expense) income, net	**($4.3)**	**$53.0**	**-108%**

Total other income (expense), net, changed from income to expense primarily due to the decrease in other income, net, associated to the Invitae shares received and sold related to the sale of ArcherDX partially offset by a reduction in interest expense after repayments of debt in 2020.

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. The fluctuation in 2021 compared to the prior year is partially attributable to the duration and level of short-term investments held during the period.

Interest expense primarily relates to debt, discussed in Note 16 "Debt" in the accompanying consolidated financial statements. The decrease in 2021 is driven by the repayment of the majority of the 2021 Notes after the first quarter of 2020.

Other income, net, for the year ended December 31, 2021, includes a $35.8 million gain recognized from the receipt and sale of the Invitae shares and related hedge, $12.0 million of income from equity method investments, $0.7 million in income, net from the changes in fair value and sale of investments held in other publicly traded companies, and a $0.3 million gain from the sale of an equity method investment, partially offset by a $9.0 million loss on foreign currency transactions.

Other income, net, was $114.3 million of income for the year ended December 31, 2020. Other income 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.

Income Tax Expense

(in millions)	**2021**	2020	% change
Income before income taxes	$625.8	$439.5	+42%
Income tax expense	$113.2	$80.3	+41%
Net income	$512.6	$359.2	
Effective tax rate	18.1%	18.3%	

In 2021 and 2020, our effective tax rates were 18.1% and 18.3%, respectively. The effective tax rates in both years reflect higher pre-tax book income due to higher operating income driven by the significant demand for solutions used in COVID-19 testing. 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. 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 in Dubai. 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 Risk Factors .

Foreign Currencies

The reporting currency of QIAGEN N.V. is the U.S. dollar. The functional currency of most of our subsidiaries 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 2021, 2020 and 2019 was $9.0 million, $4.1 million, and $5.7 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, 2021, we had cash and cash equivalents of $880.5 million and short-term investments of $184.8 million. As of December 31, 2020, we had cash and cash equivalents of $598.0 million and short-term investments of $117.2 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, 2021, cash and cash equivalents had increased by $282.5 million from December 31, 2020, primarily as a result of cash provided by operating activities of $639.0 million partially offset by cash used in investing activities of $202.4 million and cash used in financing activities of $150.4 million. As of December 31, 2021 and 2020, we had working capital of $592.1 million and $1.05 billion, respectively.

Cash Flow Summary

(in millions)	2021	2020
Net cash provided by operating activities	$639.0	$457.8
Net cash used in investing activities	($202.4)	($443.3)
Net cash used in financing activities	($150.4)	($50.1)
Effect of exchange rate changes on cash and cash equivalents	($3.7)	$4.2
Net increase (decrease) in cash and cash equivalents	$282.5	($31.4)

Operating Activities

For the years ended December 31, 2021 and 2020, we generated net cash from operating activities of $639.0 million and $457.8 million, respectively. The net increase in net cash from operating activities is primarily the result of an increase in net income and adjustments for non-cash items. While net income was $512.6 million in 2021, non-cash components in income included $214.9 million of depreciation and amortization, $38.4 million of share-based compensation, and $32.3 million of amortization of debt discount. Operating cash flows include a net decrease in operating assets and liabilities primarily due to increased inventories in order to meet the increase in demand and decreased accrued and other current liabilities and accounts payable during 2021. 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 $202.4 million of cash was used in investing activities during 2021, compared to $443.3 million during 2020. Investing activities during 2021 consisted principally of $397.7 million for purchases of short-term investments, $189.9 million in cash paid for purchases of property and equipment which includes the investments we continue to make in expanded production capacity and $16.6 million paid for intangible assets. This was partially offset by $359.6 million from the sale of short-term investments and $44.9 million returned to us from our derivative counterparties in connection with cash we had provided to them to collateralize our derivative liabilities with them as discussed in Note 14 "Derivatives and Hedging."

Cash used in investing activities during 2020 includes $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, $132.8 million purchases of property, plant and equipment, $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."

Financing Activities

For the year ended December 31, 2021, cash used in financing activities was $150.4 million compared to $50.1 million in 2020. Financing activities during 2021 includes net payments of $100.0 million for repurchases of QIAGEN shares, repayments of long-term debt including $41.1 million for two tranches of the German Private Placement (Schuldschein) that matured and $0.2 million for the remaining 2021 Notes, as well as $23.6 million paid in connection with net share settlement for tax withholding related to the vesting of stock awards. This was partially offset by $8.6 million received from our derivative counterparties to collateralize derivative assets that we hold with them.

In 2020, cash used in financing activities totaled $50.1 million and 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 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.

Other Factors Affecting Liquidity and Capital Resources

As of December 31, 2021, we carry $1.9 billion of long-term debt, of which $847.6 million is current and $1.09 billion is long-term.

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 of December 31, 2021, a total of $294.5 million is outstanding, of which $170.6 million is due in October 2022. During 2021, we paid $41.1 million when two tranches matured as described in Note 16 "Debt."

In March 2014, we issued Cash Convertible Senior Notes of which the remaining $0.2 million was paid during 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, 2021: (1) $300 million 10-year term due October 16, 2022 (3.75%); and (2) $27 million 12-year term due October 16, 2024 (3.90%).

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, 2021. The facility can be utilized in euro and bears interest of 0.550% to 1.500% 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, 2021.

On July 12, 2021, we announced our seventh share repurchase program of up to $100 million of our common shares. During 2021, we repurchased 1.9 million QIAGEN shares for $100.0 million (including transaction costs). This program ended on October 29, 2021. 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 have lease obligations, including interest, in the aggregate amount of $105.4 million, of which $23.6 million is current as of December 31, 2021. We also have purchase obligations and license commitments totaling $139.3 million and $17.8 million, respectively, and 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. These obligations are further discussed in Note 12 "Leases" and Note 20 "Commitments and Contingencies" in the accompanying financial statements.

Liabilities associated with uncertain tax positions, including interest and penalties, are currently estimated at $107.5 million as of December 31, 2021. 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. Therefore, we cannot reasonably estimate when, if ever, this amount will be paid to a government agency.

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, 2021, 2020 and 2019.

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.

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 Capital

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, and an environment and culture that allow all employees the equal opportunity for success. 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 2021, QIAGEN had 6,028 full-time equivalent employees, an increase of 7% from 5,610 at the end of 2020. We have succeeded to maintain our retention targets by maintaining a management turnover rate under 7%. For 2021, the overall turnover rate at the management level was 6.6%, with an 11.1% voluntary turnover rate for the total workforce. We believe our relationship with our employees is good.

Recognizing that our employees are the key to our success, we seek to be a great place to work. In 2021, many of our subsidiaries have been recognized as an employer of choice including in Germany, where we are recognized again as a “Top Employer” by the Top Employer Institute, a global authority on recognizing excellence in people practices. In 2021, we received the Top Employer Certificate for China, and our subsidiaries in Brazil and Mexico were again recognized as a "Great Place to Work". Our Philippines Shared Service Center won multiple employer certifications in 2021, including Asia's "Great Place to Work' and Asia's "Best Employer Brand in 2021." For the first time in 2021, our subsidiaries in the U.S. India and the Philippines were certified as a “Great Place to Work.”

In 2021, as a continued consequence of the global pandemic, a large portion of our employees continued to work remotely. For our essential workers and in our locations where employees either returned or continued to work on site, we maintained safety measures including routine on-site testing at critical facilities to reduce the risk of COVID-19 transmission.

Diversity and Inclusion

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 succeed based on their strengths and characteristics. In 2021, our workforce was composed of at least 80 nationalities with an average age of 39.4. With 49% women, we are well balanced in terms of gender on an aggregate level. Our strategic initiative on gender diversity started in late 2018 has yielded remarkable results, particularly regarding leadership positions. The participation of women in leadership roles (QIAGEN management and above) rose from approximately 28% in 2018 to 34% in 2021 (2020: 33%). We continue to work towards gender parity and are targeting a 2022 goal of 35% or more women in leadership roles. We have been listed under the 2022 Bloomberg Gender Equality Index which provides an opportunity for companies to assess progress towards parity, benchmark against peers and highlight a commitment to gender equality. Our commitment to diversity goes beyond cultural and gender diversity. Our U.S. subsidiary received a score of 100 on the Human Rights Campaign Foundation's 2022 Corporate Equality Index. QIAGEN is also a member of the Business Coalition for the Equality Act.

Employee Development

Employee development is viewed as integral to the success of creating lasting value for our customers, patients, colleagues, partners, and shareholders. We believe 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 2021, we conducted both virtual instructor-led and e-learning courses. All in-person trainings remain on hold due to the ongoing COVID-19 pandemic.

Employee Compensation

We have been committed since our beginning to attract and retain the best talent worldwide via our focus on rewarding for performance. Our compensation system fosters a focus on achieving corporate strategic initiatives as well as personal accountability. We regularly benchmark our compensation strategy to evaluate the level and mix of compensation awarded by companies and industries for a broad range of positions around the world. Our benchmarks include many peer life science and diagnostics companies. 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.

For more information about our human capital, please refer to the Sustainability page on our website at www.qiagen.com/sustainability.

Employee Worldwide

	2021	2020	2019
Americas	1,384	1,328	1,132
Europe, Middle East & Africa	3,389	3,059	2,820
Asia Pacific, Japan and Rest of World	1,255	1,223	1,144
Total	**6,028**	**5,610**	**5,096**

	2021	2020	2019
Production	30%	28%	23%
Research & Development	16%	16%	19%
Sales	37%	39%	40%
Marketing	6%	6%	6%
Administration	11%	11%	12%

Outlook

QIAGEN Perspectives for 2022

Against the backdrop of record sales in 2021, we expect demand for our non-COVID product portfolio to continue to grow during 2022, while taking a cautious view on expectations for a significant decline in COVID-19 test sales for the year. The growth in our non-COVID portfolio is expected to be driven by opportunities in the research environment amid increases in national governmental funding programs as well as a resumption in regular clinical testing for molecular diagnostics. Investments have been made to strengthen our portfolio including manufacturing upscaling projects and within research and development for menu expansion of our key platforms. These are expected to support the transition of our installed base of instruments and systems into non-COVID applications. At the same time, QIAGEN remains prepared to continue supporting the global response to the pandemic.

We plan to focus investments in our five pillars of growth with the aim to secure mid-term growth trends for these products. We are seeking to secure our leadership positions in sample technologies and for the QuantiFERON franchise, while seeking to gain market share in the three other pillars involving the QIAcuity digital PCR instruments, as well as the NeuMoDx integrated PCR systems for clinical diagnostics and the QIAstat-Dx syndromic testing platform.

Global Economic Perspectives for 2022

In January 2022, the International Monetary Fund and the World Bank both projected the world economy would grow about 4% on an annual basis.

However, this forecast has been called into doubt in light of the war in Ukraine, and the impact it has had on energy prices, global supply chains and other areas of the global economy. These impacts have combined to cause high inflation rates in many countries across the globe including rates at 40-year highs in the United States as announced by the Bureau of Labor and Statistics in April 2022. We now believe global economic growth is expected to be well below this forecast amid a risk that some regions could begin to face recessionary conditions.

Additionally, the risk continues that COVID-19 variants could emerge that prolong the pandemic and related economic disruptions. The current global economic forecast assumes that vaccination rates continue to improve worldwide and therapies become more effective during the course of 2022. Continued disruptions in the global supply chain as a result of COVID-19 and other factors could negatively impact results of operations for QIAGEN and other companies. Economic growth tends to benefit our performance, while downturn can limit spending by customers. Uncertain geopolitical conditions, including the recent and ongoing Russian invasion of Ukraine, sanctions, and other potential impacts on this region's economic environment and currencies, may cause demand for our products and services to be volatile, cause changes in our customers' buying patterns, interrupt our ability to supply products to this or other regions or limit the access of our customers to financial resources and ability to satisfy obligations to us. In 2021, net sales in Russia represented less than 1% of consolidated net sales. Currency exchange rates also positively or negatively affect QIAGEN's results as these are reported in U.S. dollars.

Industry Perspectives for 2022

The demand for testing for active SARS-CoV-2 infections using PCR and antigen products is expected to decline to a lower base level in the next phase of the COVID-19 pandemic recovery. 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 2022. Elective procedures and laboratory volumes for non-COVID issues are likely to begin to normalize.

The pandemic has accelerated the demand for genomic insights, and this has accelerated the transition from basic research into applications in medicine and other fields, delivering ever-greater value for patients and other users. As innovation drives market expansion, QIAGEN has strong product portfolios to capture opportunities in growing areas.

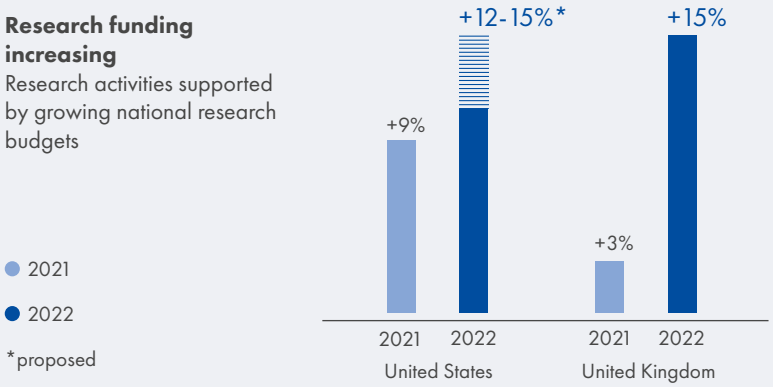
The COVID-19 pandemic has drawn attention to the fact that molecular testing can also evaluate and monitor patients for cancer, infectious diseases and other conditions. Molecular medicine is migrating from research-based institutions to hospitals and reference laboratories in need of quick, accurate results, increasing the demand for standardized tests and automated workflows. Customers are embracing 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 pharmaceutical 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 into public safety fields such as forensics and environmental monitoring.

Macro trends fueling attractive opportunities in 2022 and beyond

Research funding increasing

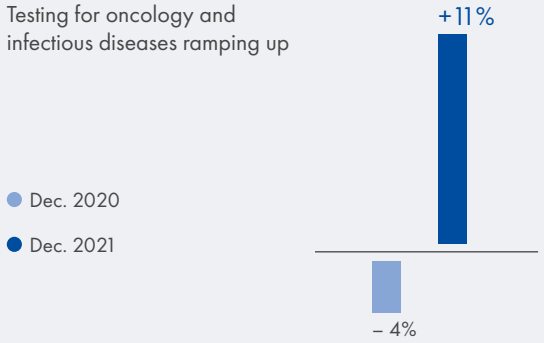
Research activities supported by growing national research budgets



Annual national research budget increases

Regular clinical testing returns to growth

Testing for oncology and infectious diseases ramping up



Routine testing change from February 2020 XIFIN volume index