RISING TO THE CHALLENGE

ANNUAL REPORT | 2020

QUIDEL

Dear Fellow Shareholders,

Before reviewing the business results of the fiscal year 2020, I want to take a moment to pay respect and extend my sympathies to all our employees, shareholders, suppliers and customers who suffered the kinds of personal losses that are immeasurable on a balance sheet – the loss of family members, friends or colleagues to the coronavirus. The pandemic has taken an enormous human toll around the world. The world grieves together. Let us honor the memories of loved ones in the work that lies ahead.

2020 will forever be indelibly linked with the COVID-19 crisis. It has been said that "crises don't build character, they reveal it." I am proud to report that at Quidel, 2020 revealed an unstoppable will to make a difference in people's lives and an endless capacity to rise to every challenge.

As soon as the sequence of the novel coronavirus was described by scientists, the Quidel Team leapt into action. Within two weeks, our R&D team developed the Lyra® molecular polymerase chain reaction (PCR) test for COVID-19 and our regulatory affairs team secured FDA Emergency Use Authorization (EUA) to serve labs, hospitals and other facilities with a highly complex designation. By May, we became the first company to receive an EUA for a rapid antigen test for decentralized, point-of-care settings that delivers results in 15 minutes. Our Sofia® SARS Antigen FIA set the bar for antigen test performance at 96.7% vs PCR. Shortly after the introduction of our Sofia product, our operations teams built manufacturing lines and managed complex supply chains to meaningfully scale our Lyra PCR production in Athens, Ohio, and quickly double our Sofia manufacturing capacity in San Diego, California to a million tests a week.

By October, our teams had again doubled our U.S. production capacity for Sofia test cartridges to over 2 million tests per week and significantly ramped production of Sofia analyzer units, as it became clear that fast, frequent antigen testing, along with mask-wearing, social distancing and self-quarantine, was key to reducing the spread of the novel coronavirus. Simultaneously, our R&D organization was first to bring out a combination assay on that same Sofia platform that enables healthcare providers to test for Influenza and SARS from the same single swab sample.

Christian Bobritchi, R&D

By year's end, our R&D teams developed six COVID-19 diagnostic assays across multiple technologies.

Our Sofia SARS Antigen FIA set the bar for antigen test performance at 96.7% vs PCR.

Ana Robles and Rosa Murados on the Triage assembly line.

Our immunoassay manufacturing processes are highly automated, with direct labor at 4% of our cost.

Our R&D organization was first to bring out a combination assay on that same Sofia platform that enables healthcare providers to test for Influenza and SARS simultaneously from the same single swab sample.

Elsa Garcia working the Triage® line.

"Our tests have saved countless lives, allowed a semblance of normalcy to resume and empowered people to take charge of their own health and safeguard others."

Still, Quidel never rested and the innovations just kept coming: Lyra Direct SARS, a faster version of our earlier test; Solana® SARS, a molecular solution for smaller hospitals and labs; and, QuickVue® SARS, a rapid visually-read test for the professional point-of-care segment that provides results in 10 minutes. By year's end, our R&D teams developed six COVID-19 diagnostic assays across multiple technologies, our regulatory affairs teams shepherded them through the FDA's challenging EUA approval process, our production teams kitted and shipped tens of millions of tests and our commercial organization assured they reached thousands of communities throughout the country.

Our tests have saved countless lives, allowed a semblance of normalcy to resume and empowered people to take charge of their own health and safeguard others. It has been a privilege to witness and work alongside such a focused and purposeful Quidel Team.

For a company our size, we have extraordinary strategic, technical and commercial competencies. Our executive team is bright, laser-focused, reads everything, and makes decisions quickly. We pick the things we choose to do very well. In terms of what is needed to develop lateral flow immunoassays, like Sofia and QuickVue SARS Antigen and the Solana SARS-CoV-2 Isothermal Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA) assay, our R&D team is as good as any on the planet. Nimble and motivated. The R&D team's processes for developing, cloning, characterizing and manufacturing antibodies are state-of-the-art, and our chemists are just as good.

Our immunoassay manufacturing processes are highly automated, with direct labor at 4% of our cost, and they are just as scalable as any larger company, while maintaining the high quality that is the hallmark of our brands. Our relationships with our distribution partners are arguably the best in the diagnostics industry, and our direct sales and marketing teams are known for their frequency of contact and impeccable follow-up, which are both critically important to our laboratory customers during these extraordinarily difficult times.

We have grown from modest beginnings to become world-class entrepreneurial innovators. From a small, but relatively successful and happy infectious disease focused company, we drew all the elements needed to play a significant role in SARS testing. Happy people are more productive, and we are executing – at speed. Our numbers for the year reflect the intensity and

efficiency of the effort. The net result is our strongest balance sheet ever and an excellent competitive position as we exited 2020.

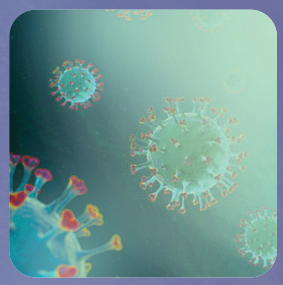
As we move into 2021, we believe the company will continue to thrive, both on our COVID and non-COVID initiatives. Let me offer a few proof points:

Total revenue for the twelve months ended December 31, 2020 was $1,661.7 million, versus $534.9 million for the same period in 2019. The 211% increase in sales was driven by greater Rapid Immunoassay and Molecular Diagnostics Solutions revenue associated with COVID-19.

Gross Profit in the twelve months ended December 31, 2020 increased to $1,348.9 million, driven by the demand for the new Sofia SARS Antigen, Sofia 2 Flu + SARS Antigen and Lyra SARS-CoV-2 products, which drove improved product mix. In addition, higher production volumes contributed to increased manufacturing overhead absorption, which offset increases in spend required to expedite the production ramp. Gross margin improved to 81% due to the same factors. These results speak to the efficiencies we have achieved while maintaining constant vigilance in every aspect of quality assurance.

"Our goal all along has been to do the right thing for families and communities. To enable physicians to chart courses of treatment and give consumers information to better manage their health and wellness."

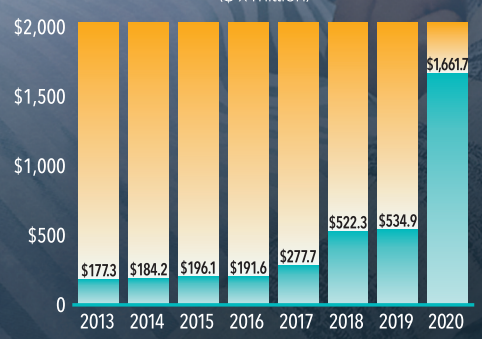
We had only minimal QuickVue and Solana SARS revenues in 2020, as they both were cleared for EUA in December. But notably, we received an EUA in Q1 2021 for sale of our QuickVue® At-Home OTC COVID-19 Test to consumers. This over-the-counter (OTC) assay shows excellent performance, is easy-to-use and provides results in 10 minutes. Our decades of experience with influenza testing have taught us that respiratory viruses are survivors, and they survive through mutations that can evade current vaccines. While we cannot know today what the novel coronavirus will look like years from now, we can anticipate that it will need to be

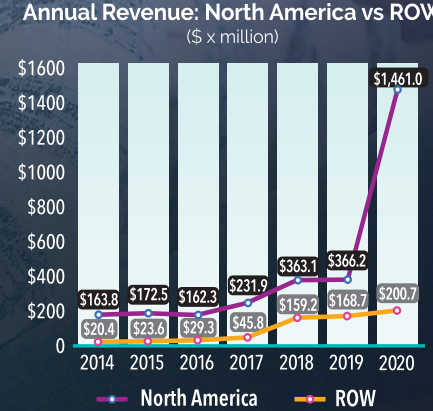


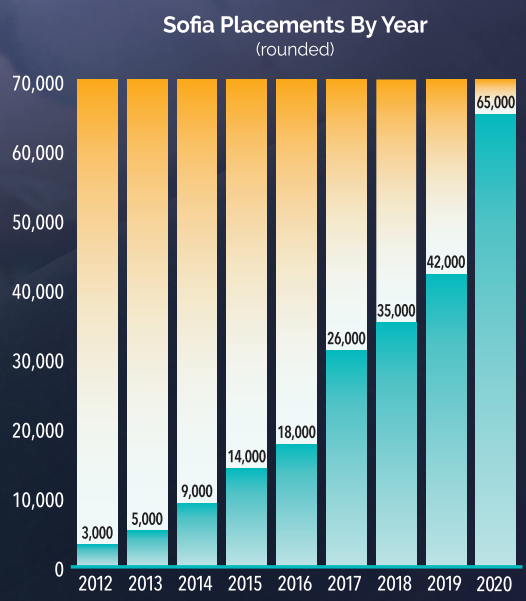
Our 211% increase in sales was driven by greater Rapid Immunoassay and Molecular Diagnostics Solutions revenue associated with COVID-19.

Sofia Q features a sleek, miniaturized design but reads the same Sofia SARS-CoV-2 rapid antigen tests as the Sofia 2, with equal accuracy.

QuickVue At-Home OTC COVID-19 Test is an easy-to-use at home test that provides results in 10 minutes.







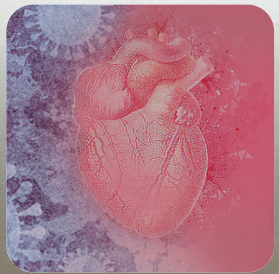
detected, diagnosed and tracked closely. Rest assured, Quidel will be there all the way, with a suite of diagnostic technologies that can be deployed from hospitals to homes, giving clinicians and consumers the timely information they need to safeguard themselves and their families.

We are not waiting for the OTC testing revolution; we intend to lead it. We recently started the buildout of a new manufacturing facility in Carlsbad, CA. The 128,000 square foot facility will be the company's highest-volume production facility and will begin operations in the second half of 2021, initially with a mission to produce more than 50 million QuickVue rapid antigen tests per month, or 600 million tests per year at full capacity, for the detection and diagnosis of COVID-19 infections. Ultimately, as we ramp production dramatically, we will get the cost down so that the average family in America can afford to go to their retail store and bring home QuickVue At-Home OTC COVID-19 tests to run as they deem necessary. And just as the pandemic has accelerated and amplified the revolution of remote work, we expect other products in our portfolio to enter new markets, such as OTC, making at-home testing for Influenza A+B, RSV, Strep and other conditions mainstream and routine. We believe this surge of home testing is inevitable and will sustain robust QuickVue production operations for many years to come.

We view QuickVue as just one opportunity in front of us to address the OTC space. We have been intensely focused in 2020 and Q1 of 2021 on the development of our third-generation version of the Sofia instrumented system – Sofia Q. Previously code-named "Sniffles," Sofia Q features a sleek, miniaturized design but reads the same Sofia SARS-CoV-2 rapid antigen tests as the Sofia 2, with equal accuracy. We intend for Sofia Q to be very affordably priced and to further democratize access to the many benefits of our Sofia SARS rapid antigen tests as well as our portfolio of Sofia tests for

We recently started the buildout of a new manufacturing facility in Carlsbad, CA. The 128,000 square foot facility will be the company's highest-volume production facility and will begin operations in the second half of 2021.

We are seeing increased demand for our d-dimer test related to the concerns that COVID-19 can drive clotting related disorders.



influenza, hCG, Lyme, RSV, Strep and other conditions. Our plans to manufacture 100,000 Sofia Q units by the end of Q2 2021 will significantly extend our rapidly growing installed base of 65,000 Sofia 2 instruments, improving market share.

Finally, we are seeing increased demand for our d-dimer test related to the concerns that COVID-19 can drive clotting related disorders. Looking ahead, we see considerable potential in the TriageTrue® High Sensitivity Troponin I Test we are developing for POC detection of heart muscle injury. Stay tuned for more on this in 2021 and 2022.

Last (for this update letter), but far from least is the coming dawn of what could be the most important flagship product in the history of the company, Savanna.® It's a multiplex molecular analyzer that we think will decentralize PCR testing across integrated delivery networks. The system uses proven molecular techniques – magnetic bead-based nucleic acid isolation and real time PCR – which enable customers to quickly analyze up to 12 targets, plus controls, in a single assay run. Savanna can test for analytes qualitatively and quantitatively as well as test for particular pathogens, and simultaneously determine their antibiotic resistance statuses.

This gives us absolute flexibility for the assays that we can develop for Savanna. And the Savanna test procedure is a true sample-in to result-out operation, making it ideal for moderate complexity labs, hospitals, physician offices, urgent care clinics and a host of other locations and applications. Feedback from customers has been tremendous. We began clinical trials for the instrument and respiratory panel in mid-February and expect to embark on a limited launch, manufacturing approximately 1,000 instruments and a little over 1 million cartridges by the end of this year.

Our QuickVue SARS Antigen Test on the line.

Savanna is a multiplex molecular analyzer that we think will decentralize PCR testing across integrated delivery networks.

2020 has truly been a transformative year for Quidel. But we have remained true to our purpose and our principles.

Our goal all along has been to do the right thing for families and communities. To enable physicians to chart courses of treatment and give consumers information to better manage their health and wellness.

With the COVID-19 pandemic, that mission has grown significantly in both urgency and scale. And we have grown with it. Striving to make the greatest impact we can. Democratizing diagnostic testing so that healthcare providers and first responders can do their jobs safely, so that grandmas and grandpas can reunite safely with their loved ones, so that students can get back to class, athletes can return to competition and our economy can be restored as more and more people can safely return to work.

And while the journey is long, and there is much to do ahead of us, we are well on our way. I have no doubt that the people of Quidel have the ingenuity, resilience and unwavering dedication to further transform our company and advance diagnostic medicine to inform the path to better health for people and communities around the world.

Sincerely,

Douglas C. Bryant

President and CEO
Quidel Corporation
April 2021

Scientists from R&D were featured in our Quidel Women's Leadership Network February newsletter: Gabrielle Cruz, Lauren Hedges, Serena Chen, Lisa Millar, Kelly Brooks, Ashlee King, Irene Blandy, and Beatrice Avalos.

Andrew Kim, Lead Manufacturing Technician on the Triage line.

Filming the Triage production line: Jeannine Mason, Jeff Landie and Michael Williams.

From the cover: Rita Ramirez, Elisa Winterbourne and Jessica Battle inspecting product on Sofia line 5.

The SARS/COVID-19 tests described in this report have not been FDA cleared or approved, but have been authorized by the FDA under an Emergency Use Authorization (EUA) for use as directed under each EUA. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from N/A to N/A
Commission file number: 0-10961

QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-2573850**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9975 Summers Ridge Road, San Diego, California 92121
(Address of principal executive offices, including zip code)

858-552-1100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	QDEL	The Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $8,173,089,184 based on the closing sale price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter.
As of February 5, 2021, 42,319,115 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

(To the Extent Indicated Herein)

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2021 Annual Meeting of Stockholders (scheduled to be held on May 18, 2021) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K

QUIDEL CORPORATION

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020

TABLE OF CONTENTS

A Warning About Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, those discussed in this Annual Report on Form 10-K in Part I, Item 1A "Risk Factors." Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. Forward-looking statements in this Annual Report include, among others, statements concerning: our outlook for the upcoming fiscal year regarding revenue growth, gross margins and earnings; the impact of the COVID-19 pandemic on our business, operations, strategy, liquidity and capital resources; projected capital expenditures for the upcoming fiscal year and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; that we may incur additional debt or issue additional equity; our strategy, goals, initiatives and objectives including, but not limited to, our entry into the over-the-counter market; anticipated new product offerings related to existing platforms; the anticipated beneficial attributes of products and platforms under development; anticipated new product and development results; our exposure to claims and litigation, including litigation currently pending against us involving Beckman Coulter; that we expect to continue to depend on a few key distributors for sales of our products; expected growth and the sources of that growth; the impact of new accounting standards; that point-of-care testing is increasing; that clinical reference laboratories will continue to be a competitive threat; that we will continue to make substantial expenditures for sales and marketing, manufacturing and product research and development activities; that integration costs will decline; industry consolidation and competition trends; competition for management and key personnel; the sufficiency of our facilities; the sufficiency of our insurance and our exposure to claims and litigation; our intention to not pay dividends; that we will continue to obtain licenses from third parties; and our intention to continue to evaluate technology and acquisition opportunities. The risks described under "Risk Factors" in Item 1A of this Annual Report and elsewhere herein and in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

Part I

Item 1. Business

All references to "we," "our," and "us" in this Annual Report refer to Quidel Corporation and its subsidiaries.

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories: rapid immunoassay, cardiometabolic immunoassay, molecular diagnostic solutions and specialized diagnostic solutions. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products through a network of distributors and through a direct sales force. We operate in one business segment that develops, manufactures and markets our four product categories.

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1983. Since such time, our product base and technology platforms have expanded through internal development and acquisitions of other products, technologies and companies. Our diagnostic solutions aid in the detection and diagnosis of many critical diseases and other medical conditions, including infectious diseases, cardiovascular diseases and conditions, women's health, gastrointestinal diseases, autoimmune diseases, bone health and thyroid diseases.

Corporate Information

We are a corporation, originally incorporated as Monoclonal Antibodies, Inc. in California in 1979 and re-incorporated as Quidel Corporation in the State of Delaware in 1987. In 2017, we acquired the Triage® MeterPro® Cardiovascular (CV) and toxicology business ("Triage Business"), and B-type Naturietic Peptide (BNP) assay business run on Beckman Coulter analyzers ("BNP Business" and, together, the "Triage and BNP Businesses") from Alere Inc. ("Alere"), which added an extensive cardiovascular and toxicology menu to our innovative medical diagnostics portfolio.

Our executive offices are located at 9975 Summers Ridge Road, San Diego, California 92121, and our telephone number is (858) 552-1100. This Annual Report and each of our other periodic and current reports, including any amendments thereto, are available, free of charge, on our website, www.quidel.com, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information contained on our website or on the SEC website is not incorporated by reference into this Annual Report and should not be considered part of this Annual Report.

Business Strategy

Our primary mission is to advance diagnostics to improve human health. Our strategy is to target market segments that represent significant total market opportunities, and in which we can be successful by applying our expertise and know-how to develop differentiated technologies and products.

Our diagnostic testing solutions are designed to provide specialized results that serve a broad range of customers, by addressing the market requirements of ease of use, reduced cost, increased test accuracy and reduced time to result. Our current approach is to offer products in the following product categories:

- rapid immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, eye health settings, pharmacies, other urgent care or alternative site settings to include over the counter commencing in 2021;
- cardiometabolic immunoassay tests for use in physician offices, hospital laboratories and emergency departments, and other urgent care or alternative site settings;
- molecular diagnostic tests for use in hospitals, moderately complex physician offices, laboratories and other settings; and
- specialized diagnostic solutions, including direct fluorescent assays ("DFA") and culture-based tests for the clinical virology laboratory and other products serving the bone health, autoimmune and complement research communities.

In order to achieve our mission, our strategy is to do the following:

- focus on innovative products and markets and leverage our core competency in new product development for our QuickVue®, Sofia® and Triage® immunoassay brands and next-generation products;

- leverage our manufacturing expertise to address increasing demand for our products, including through expanded manufacturing capacity;
- utilize our molecular assay development competencies to further develop our molecular diagnostics franchise that includes distinct testing platforms, such as Lyra®, Solana® and Savanna®; and
- strengthen our position with distribution partners and our end-user customers to gain more emphasis on our products and enter new markets.

Our current initiatives to execute this strategy include the following:

- provide products that can compete effectively in the healthcare market where cost and quality are important;
- focus our research and development efforts on three areas:
  - new proprietary product platform development;
  - the creation of new and improved products for use on our established platforms to address unmet clinical needs, and
  - pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy;
- leverage our international infrastructure and enhance our global footprint to support our international operations and future growth;
- strengthen our market and brand leadership in current markets by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;
- pursue alternative markets for point-of-care diagnostics;
- create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets;
- further refine our manufacturing efficiencies and productivity improvements to increase profit; and
- pursue potential acquisitions to support our strategic initiatives.

The Overall Market for *In Vitro* Diagnostics

Customers for *In Vitro* Diagnostics ("IVD") products are primarily centralized laboratories and decentralized POC or alternate settings.

Centralized testing market

The centralized in vitro diagnostic testing process typically involves obtaining a specimen of blood, urine or other sample from the patient and sending the sample from the healthcare provider's office, hospital unit or clinic to a central laboratory. In a typical visit to the physician's office, after the patient's test specimen is collected, the patient is usually sent home and receives the results of the test several hours or days later. The result of this process is that the patient may leave the physician's office without confirmation of the diagnosis and the opportunity to begin potentially more effective immediate care.

Decentralized POC market

POC testing for certain diseases or conditions has become an accepted adjunct to central laboratory and self-testing. The professional POC market is comprised of two general segments: decentralized testing in non-institutional settings, such as physicians' offices and institutional settings, such as hospitals (e.g., emergency rooms and bedside).

- Out-of-hospital testing sites consist of physicians' office laboratories, nursing homes, pharmacies, eye health offices, retail clinics and other non-institutional, ambulatory settings in which healthcare providers perform diagnostic tests.
- Hospital POC testing is accepted and growing and is generally an extension of the hospital's central laboratory. Hospitals in the U.S. have progressively sought to reduce the length of patient stays and, consequently, the

proportion of cases seen as outpatients has increased. If the U.S. experience is representative of future trends, emergency departments and other critical care units such as intensive care units, operating rooms, trauma and cardiac centers are increasingly becoming the principal centers for the management of moderate and severe acute illness.

The decentralized POC market utilizes a large variety of IVD products ranging from moderate-sized instrumented diagnostic systems serving larger group practices to single-use, disposable tests. We believe POC testing is increasing due to its clinical benefit, fast results, cost-effectiveness and patient satisfaction.

We believe that the growth in POC testing is in part due to evolving technological improvements creating high quality tests with laboratory accuracy and POC ease-of-use, some of which are capable of being granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Over-the-counter market/Self-testing

There is an established market for self-testing that is available directly to consumers in the over-the-counter market in the U.S. and in other countries. In this market, users can purchase and administer tests directly at home and in many cases without a prescription or a visit to a physician. We have not historically sold our products into this market but plan to launch products through retail and over the counter channels in 2021.

Products

We provide diagnostic testing solutions under various brand names, including, among others, the following: Quidel®, QuickVue®, QuickVue+®, Sofia®, Triage®, Solana®, Virena®, MicroVue™, Lyra®, FreshCells™, D3®, FastPoint®, ReadyCells®, Super E-Mix™, InflammaDry®, AdenoPlus®, ELVIRA®, ELVIS® and Thyretain®.

System Platforms

Our diagnostic testing solutions are separated into our four product categories: rapid immunoassay, cardiometabolic immunoassay, molecular diagnostic solutions and specialized diagnostic solutions. The key product categories and platforms are described below:

Rapid Immunoassay

Sofia and Sofia 2 Analyzers. Sofia is the brand name for our fluorescent immunoassay ("FIA") systems. The easy-to-use Sofia and Sofia 2 analyzers combine unique software and Sofia FIA tests to yield an automatic, objective result that is readily available on the instrument's screen, in a hard-copy printout, and in a transmissible electronic form that can network via a lab information system to hospital and medical center databases. We launched the Sofia analyzer in 2011 and Sofia 2 in 2017. These systems provide for different operational modes to accommodate both small and large laboratories as well as other features designed to facilitate use in a variety of healthcare settings, including hospitals, medical centers, and small clinics. Sofia 2 systems include additional benefits and features at a cost point that allows us to better address the lower-volume segment of the diagnostic testing market. Sofia 2 analyzers also incorporate enhanced optics, which provide added performance benefits and enable positive test results to be read in as few as three minutes. In 2021, we also plan to launch a Sofia Q platform that offers similar features and benefits to the Sofia analyzers in a smaller and less expensive format.

QuickVue. QuickVue is the brand name for our rapid, visually-read, lateral flow immunoassay products. We have been a leader in the development and production of high-quality lateral flow diagnostics since the early 1990s and offer a broad portfolio of products to diagnose a wide variety of infectious diseases and medical conditions.

InflammaDry and AdenoPlus. The InflammaDry and AdenoPlus products are rapid, lateral-flow based, POC products for the detection of infectious and inflammatory diseases and conditions of the eye. InflammaDry is a test that detects elevated levels of MMP-9, a key inflammatory marker for dry eye. AdenoPlus is a test that differentiates between a viral and bacterial infection of acute conjunctivitis (pink eye).

Cardiometabolic Immunoassay

Triage MeterPro. Triage MeterPro is our portable testing platform that runs a comprehensive menu of tests that enable physicians to promote improved health outcomes through the rapid diagnosis of critical diseases and health conditions, as well as the detection of certain drugs of abuse. This system aids in the diagnosis, assessment and risk stratification of patients having

critical care issues, including congestive heart failure, acute coronary syndromes, acute myocardial infarction ("AMI") and can reduce hospital admissions and improve clinical and economic outcomes. Triage cardiovascular rapid tests include immunoassays for B-type Natriuretic Peptide (BNP), creatine kinase-MB (CK-MB), d-dimer, myoglobin, troponin I and N-terminal pro-Brain Natriuretic Peptide (NT-proBNP). Triage tests for troponin I, high sensitivity Troponin I, PlGF and NT-proBNP, as well as certain test panels which include a combination of immunoassays, are not available for sale in the United States.

We also offer a version of the Triage BNP Test for use on Beckman Coulter lab analyzers.

In addition to the cardiovascular menu, we offer urine-specific screening tests for the detection of drug and/or the urinary metabolites for multiple drug classes, including our new Triage TOX Drug Screen and a PlGF test for diagnosis of preterm pre-eclampsia in pregnant women.

Molecular Diagnostic Solutions

Lyra. Our open system molecular assays run on several thermocyclers currently on the market. Lyra Molecular Real-Time Polymerase Chain Reaction ("PCR") assays provide important benefits to the customer, including, among others, room temperature storage, reduced process time, and ready-to-use reagent configurations. These include several assays as noted in our medical and wellness categories discussion below.

Solana. The Solana system was developed using our proprietary isothermal Helicase Dependent Amplification ("HDA") technology. Solana is an easy to run amplification and detection system that has the ability to concurrently run up to 12 assays at a time as noted in our medical and wellness categories discussion below.

Savanna. We are developing the Savanna system as a low-cost, fully-integrated system with sample in/result out simplicity. The system is expected to be able to run either PCR or HDA assays from multiple sample types.

Specialized Diagnostic Solutions

Virology. We provide a wide variety of traditional cell lines, specimen collection devices, media and controls for use in laboratories that culture and test for many human viruses, including, among others, respiratory and herpes family viruses. We provide cell-based products under the FreshCells brand in multiple formats, including tubes, shell vials and multi-well plates. Our Virology product category includes the Food and Drug Administration ("FDA") cleared bioassay, Thyretain, which is used for the differential diagnosis of an autoimmune disease called Graves' Disease.

Specialty Products. We provide a variety of biomarkers for bone health and produce both clinical and research products for the assessment of osteoporosis and the evaluation of bone resorption/formation, which, including our metabolic bone markers, are used to monitor the effectiveness of therapy in pharmaceutical and related research. In the area of autoimmune disease, we have developed Enzyme Linked Immunosorbent Assays ("ELISA") and reagents for the detection of activation products from the three main Complement Pathways. Assays are developed on a microwell platform and are currently marketed to clinicians and researchers. We currently sell these products both directly and through select distributors throughout the world under the Quidel and MicroVue brands.

Connectivity and Data Management

Virena. Virena is a wireless cellular data management and surveillance system that operates as a cloud-based solution connecting Sofia and Solana instruments across a healthcare system and automatically transmitting de-identified test results to a secure database. With Virena, a health system, physician office laboratory ("POL"), urgent care center or retail clinic has the ability to compile, analyze, map and generate reports of de-identified test results improving operational efficiencies, quality and patient outcome initiatives.

Medical and Wellness Categories

Our products address the following medical and wellness categories, among others:

Infectious Diseases

COVID-19. We offer a variety of products designed to detect the novel coronavirus (COVID-19) on various platforms.

Sofia and Sofia 2 Analyzers. We offer a variety of point-of-care assays for the detection of COVID-19 on our Sofia and Sofia 2 Analyzers. The Sofia SARS Antigen Fluorescent Immunoassay (FIA) uses advanced immunofluorescence-based lateral flow technology in a sandwich design for qualitative detection of nucleocapsid protein from SARS-CoV-2. The Sofia 2 Flu + SARS Antigen FIA is a rapid point-of-care test to be used with the Sofia 2 Fluorescent Immunoassay Analyzer for the rapid, simultaneous qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, influenza A and influenza B in direct nasopharyngeal and nasal swab specimens.

QuickVue. Our QuickVue® SARS Antigen test is a point-of-care assay for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares swab specimens.

Lyra. We offer multiple products to aid in the detection of the novel coronavirus with our Lyra products. Our Lyra SARS-CoV-2 Assay and Lyra Direct SARS-CoV-2 Assay are real-time RT-PCR tests intended for the qualitative detection of nucleic acid from SARS-CoV-2 for various sample types, with and without extraction.

Solana. Our Solana® SARS-CoV-2 Assay, an isothermal Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA) assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and nasal swab specimens. The Solana system can generate results for 12 tests at a time in less than 30 minutes.

Influenza. We offer a variety of products designed to detect the viral antigens of influenza type A and B utilizing fluorescent immunoassay, lateral flow and molecular technologies. Our Sofia Influenza A+B test, used in conjunction with our Sofia and Sofia 2 analyzers, and our QuickVue influenza tests are rapid, qualitative tests for the detection of the viral antigens of influenza type A and B, the two most common types of the influenza virus. In addition, we offer molecular testing options with Solana Influenza A+B assay and our Lyra Influenza A+B real-time PCR assay.

Streptococci. We offer a number of products designed to detect Streptococcal infections utilizing fluorescent immunoassay, lateral flow and molecular technologies. Our Sofia Strep A and Strep A+ fluorescent immunoassays, used in conjunction with our Sofia and Sofia 2 analyzers, and our QuickVue Strep A tests are intended for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. In addition, we offer molecular options with our Solana Group A Strep and Solana Strep Complete assays, which allow for the rapid, qualitative detection of Group A and for Strep Complete, also the detection of pyogenic Group C or G Strep, utilizing our molecular HDA technology. Our Lyra Direct Strep Assay is a multiplex real-time PCR assay that detects and differentiates between Group A and pyogenic C or G Streptococcal throat infections.

RSV (and hMPV). Our Sofia RSV test and our QuickVue RSV test are rapid immunoassay tests for Respiratory Syncytial Virus ("RSV"). In addition, we offer molecular testing options with our Solana RSV + human metapneumovirus (hMPV) test and our combo Quidel Lyra RSV + human metapneumovirus (hMPV) test. The majority of upper respiratory tract infections in children is caused by viruses, and RSV is generally recognized as a frequent agent responsible for these infections and shares overlapping symptoms with hMPV.

Herpes and Herpes Family. We offer several products designed to detect various herpes simplex virus ("HSV") and herpes family viruses utilizing molecular and cell culture technologies. We offer our Solana HSV-1+2/VZV Assay, used in conjunction with our Solana instrument, for the detection of HSV type 1, HSV type 2, and varicella-zoster virus ("VZV"). We also offer our Lyra Direct HSV 1+2/VZV assay. In addition, our proprietary engineered cell culture system, ELVIS HSV, is an FDA cleared and highly sensitive system for the isolation and detection of HSV types 1 and 2. We also provide a multiplex cell culture solution using a propriety cell platform called H&V-Mix™ that is used to isolate HSV, VZV and Cytomegalovirus, all in the herpes family of viruses. Antibody detection and identification of each of these viruses can be performed with FDA-cleared antibody products provided under the D3 DFA brand. HSV is a widespread sexually transmitted infection. VZV is a DNA virus of the family Herpesviridae; infection results in chickenpox (varicella) and may lead to complications such as pneumonia and may reactivate later in life to produce shingles.

Multiplex Respiratory. Our cell culture and DFA detection solutions, including D3 FastPoint technology, are used by reference laboratories, public health labs and acute care hospitals to detect eight major viral respiratory pathogens. Our proprietary cell culture platform R-Mix™ combined with our D3 Ultra DFA antibody kit, detects Influenza A and B, RSV, Adenovirus and Parainfluenza types 1, 2 and 3, with turn-around times between 16 and 48 hours. The same D3 Ultra DFA antibody kit can also be used for direct specimen testing for those viruses with turn-around times in under 90 minutes. Our D3 FastPoint antibody kit detects eight viruses, with human metapneumovirus added to the testing menu, and provides laboratories, in a direct specimen testing format, the ability to produce virus identification in under 25 minutes from specimen receipt.

Lyme. Our Sofia Lyme FIA, used in conjunction with our Sofia analyzers, is used to aid in the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi from serum and plasma specimens from patients suspected of B. burgdorferi infection and is intended for use to aid in the diagnosis of Lyme disease, a tickborne disease. In 2018, we received 510(k) clearance and CLIA waiver from the FDA to market Sofia 2 Lyme FIA, which is used with the Sofia 2 Fluorescent Immunoassay analyzer for the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi from finger-stick whole blood specimens from patients suspected of B. burgdorferi infection. In addition, our Sofia 2 Lyme+ assay is CE marked for use in the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi, Borrelia garinii, and Borrelia afzelii from serum and plasma specimens. These tests are intended for use with the Sofia 2 analyzer to aid in the diagnosis of Lyme disease in the U.S. and European markets.

S. pneumoniae. Our Sofia S. Pneumoniae FIA, used in conjunction with our Sofia analyzer, was CE Marked for sale in the European market in 2016. The assay is used to aid in the detection of both pneumococcal pneumonia and pneumococcal meningitis. Streptococcus pneumoniae is a leading cause of community-acquired pneumonia and bacterial meningitis.

Legionella. Our Sofia Legionella FIA, used in conjunction with our Sofia analyzer, is CE Marked for sale in the European market. The assay is used to aid in the detection of Legionella pneumophila serogroup 1 antigen, which is the major causative agent of Legionnaires' disease.

Bordetella Pertussis. Pertussis, or whooping cough, is a very contagious disease caused by the Bordetella pertussis bacteria. Our Solana Bordetella Complete Assay is used for the qualitative detection and differentiation of Bordetella pertussis and Bordetella parapertussis nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having a respiratory tract infection attributable to Bordetella pertussis and Bordetella parapertussis.

Adenovirus and Parainfluenza. Quidel offers the Lyra Adenovirus Assay, a real-time PCR test for the qualitative detection of human adenovirus (HAdV) viral DNA, and our Lyra Parainfluenza Assay, a real-time PCR test for the qualitative detection and identification of Parainfluenza virus infections for types 1, 2 or 3 viral RNA.

Cardiology

The cardiology diagnostic market includes the markets for heart failure diagnostics, coronary artery disease risk assessment, coagulation testing and acute coronary syndrome. Our 2017 acquisition of the Triage and BNP Businesses have positioned us to become a leader in this market. The Triage system consists of a portable fluorometer that interprets consumable test devices for cardiovascular conditions. The Triage cardiovascular tests include the following:

Triage BNP Test. An immunoassay to be used with the Triage® MeterPro that measures B-type Natriuretic Peptide (BNP) in whole blood or plasma, used as an aid in the diagnosis and assessment of severity of heart failure. The test is also used for the risk stratification of patients with acute coronary syndromes and heart failure.

Triage Cardiac Panel. An immunoassay for the quantitative determination of CK-MB, myoglobin and troponin I in whole blood or plasma, as an aid in the diagnosis of AMI.

Triage Profiler S.O.B. An immunoassay for use as an aid in the diagnosis of myocardial infarction (MI), the diagnosis and assessment of severity of congestive heart failure, the assessment and evaluation of patients suspected of having disseminated intravascular coagulation and thromboembolic events, including pulmonary embolism and deep vein thrombosis, and the risk stratification of patients with acute coronary syndromes.

Triage D-Dimer Test. An immunoassay for use as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events, including pulmonary embolism and deep vein thrombosis.

Triage NT-proBNP Test. An immunoassay for the quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) in Ethylenediaminetetraacetic Acid (EDTA) anticoagulated whole blood and plasma specimens. The test is used

as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is also used as an aid for the risk stratification of patients with heart failure and the risk stratification of patients with acute coronary syndromes (ACS).

Triage Troponin. Troponin I, T and C are protein subunits that make up the troponin complex, which is integral to the regulation of myofibril contraction in skeletal and cardiac muscle cells. Cardiac troponin I assays are commonly used as aids in the diagnosis of MI, which is injury to cardiac muscle cells caused by ischemia.

TriageTrue High Sensitivity Troponin. The TriageTrue High Sensitivity Troponin I Test is our latest generation of troponin assay used for the quantitative determination of troponin I in whole blood and plasma specimens, anticoagulated with EDTA, and features a redesigned cartridge that greatly improves assay sensitivity and precision that are critical to the performance of high sensitivity troponin testing. The test is to be used as an aid in the diagnosis of MI.

Triage PLGF Test. An immunoassay for use as an aid in the early and accurate diagnosis of preterm pre-eclampsia in pregnant women.

Triage BNP Test for Beckman Analyzers. We also offer a version of our Triage BNP Test for use on Beckman Coulter lab analyzers.

Thyroid

Graves' Disease. Our FDA cleared bioassay called Thyretain is used for the differential diagnosis of an autoimmune disease called Graves' Disease. Graves' Disease is caused by antibodies that stimulate the thyroid hormone receptors to create a hyperthyroid condition causing symptoms that include heart palpitations, unexplained weight loss, anxiety, depression and fatigue. Graves' Disease is considered the most common autoimmune disorder in the U.S. according to an article published in the New England Journal of Medicine and it predominantly affects women. Thyretain is sold to reference laboratories and select acute care hospitals.

Autoimmune Thyroiditis. In 2017, we received the CE Mark for our Thyretain TBI Reporter BioAssay for the qualitative detection of blocking autoantibodies to the thyroid-stimulating hormone receptors (TSHR) in serum. The assay enables highly complex laboratories to diagnose autoimmune thyroiditis in just a few days, compared to traditional detection methods that could take months or even years.

Women's and General Health

Pregnancy. Our Sofia hCG fluorescent immunoassay and our QuickVue pregnancy tests are used for the qualitative detection of hCG in serum or urine for the early detection of pregnancy. The early detection of pregnancy enables the physician and patient to institute proper care, helping to promote the health of both the mother and the developing embryo.

Chlamydia. Our QuickVue Chlamydia test is a lateral flow immunoassay for the rapid, qualitative detection of Chlamydia trachomatis from endocervical swab and cytology brush specimens. The test is intended for use as an aid in the presumptive diagnosis of Chlamydia. Chlamydia trachomatis is responsible for the most widespread sexually transmitted disease in the U.S. Over one-half of infected women do not have symptoms and, if left untreated, Chlamydia trachomatis can cause sterility.

Group B Streptococcus (GBS). Our Solana GBS Assay is used in conjunction with our Solana instrument, for the direct, qualitative detection of Group B Streptococcus from enriched broth cultures of specimens from antepartum women. GBS is commonly carried by pregnant women and can be transmitted to newborns at delivery, resulting in potential life-threatening illness. It is recommended that all pregnant women be tested for GBS during pregnancy.

Trichomonas. Our Solana Trichomonas Assay is used in conjunction with our Solana instrument, to aid in the diagnosis of trichomoniasis, a sexually transmitted disease attributable to infection from the Trichomonas vaginalis parasite. Trichomoniasis affects millions of people in the U.S., is more common in women, and can be treated with antibiotics upon diagnosis.

Bone Health. Osteoporosis is a systemic skeletal disease characterized by low bone mass and deterioration of the microarchitecture of bone tissue, with a consequent increase in bone fragility and susceptibility to fractures. The risk for fracture increases exponentially with age. A key set of parameters in the monitoring of osteoporosis, both before and after therapy, are biochemical markers of bone metabolism. As a leader in the research space with our biomarkers for bone health, we produce both clinical and research products for the assessment of osteoporosis and the evaluation of bone resorption/

formation, which, including our metabolic bone markers, are used by physicians to monitor the effectiveness of therapy in pharmaceutical and related research.

Eye Health

Our InflammaDry and AdenoPlus products are rapid, lateral-flow based, POC products for the detection of infectious and inflammatory diseases and conditions of the eye. InflammaDry is a test that detects elevated levels of MMP-9, a key inflammatory marker for dry eye. AdenoPlus is a test that differentiates between a viral and bacterial infection of acute conjunctivitis (pink eye).

Gastrointestinal Diseases

Clostridium difficile. Our Solana C. difficile Assay is used in conjunction with our Solana instrument, for the direct, qualitative detection of the Clostridium difficile DNA in unformed stool specimens of patients suspected of having Clostridium difficile-infection (CDI). In addition, we sell our Lyra Direct C. difficile Assay, a qualitative, multiplexed real-time PCR test for the detection of Clostridium difficile Toxin A or Toxin B genes approved for use on a variety of real-time PCR instruments. Clostridium difficile can be a life-threatening bacterial infection, especially for the elderly and patients on a prolonged antibiotic regimen.

Enterovirus. Enteroviruses reproduce initially in the gastrointestinal tract before spreading to other organs such as the nervous system, heart and skin. Enteroviruses can also infect the respiratory tract. Enteroviruses such as Coxsackievirus A16 are referred to as Hand, Foot and Mouth Disease and commonly affect infants and children. Our indirect fluorescent antibody ("IFA") products sold under the name Super E-Mix and D3 IFA Enterovirus kit are used by reference laboratories and acute care hospitals.

Immunoassay fecal occult blood. Our QuickVue fecal immunochemical test is a rapid test intended to detect the presence of blood in stool specimens. Blood in the stool is an indication of a number of gastrointestinal disorders, including colorectal cancer.

Helicobacter pylori ("H. pylori"). H. pylori is the bacterium associated with patients diagnosed with peptic ulcers. *H. pylori* is implicated in chronic gastritis and is recognized by the World Health Organization as a Class 1 carcinogen that may increase a person's risk of developing stomach cancer. Our QuickVue rapid test is a serological test that measures antibodies circulating in the blood caused by the immune response to the H. pylori bacterium.

Toxicology

The toxicology testing market includes testing for substance use, misuse and abuse, including testing in connection with pain management and opioid cessation therapy. The ability to rapidly identify the impact of drug use on a patient's clinical presentation as well as securely monitor a patient's therapy compliance is critical to the substance abuse testing market. Our Triage TOX Drug Screen provides qualitative results for the determination of the presence of drug and/or the major metabolites in urine including assays for acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, THC and tricyclic antidepressants. In addition, in 2019, we launched our new Triage TOX Drug Screen, which uses distinct immunoassays for the simultaneous detection of drug and/or the urinary metabolites for multiple drug classes.

Research and Development

We continue to focus our research and development efforts on three areas:

- new proprietary product platform development,
- the creation of new and improved products for use on our established platforms to address unmet clinical needs, and
- pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy.

Research and development expenses were approximately $84.3 million, $52.6 million, and $51.6 million for the years ended December 31, 2020, 2019 and 2018, respectively. We anticipate that we will continue to devote a significant amount of financial resources to product and technology research and development in the foreseeable future.

Marketing and Distribution

Our current business strategy is designed around serving the continuum of healthcare delivery needs globally, starting with POC clinicians located in doctor's office practices, to moderately complex POLs, through the highly complex environment in hospital and clinical reference laboratories in North America and a variety of settings internationally.

Within the inherent operational diversity of these various segments, we focus on ensuring market leadership and providing points of differentiation by specializing in the diagnosis and monitoring of selected disease states and conditions. Our marketing strategy includes ensuring that our key product portfolios are supported by clinical validation and health economic and outcomes research that demonstrates to hospitals, laboratories, acute care facilities and POC clinicians that our tests deliver fast, high quality results, are cost-effective to use, and improve patient outcomes.

Our North America distribution strategy takes into account the fact that the POC market is highly fragmented, with many small or medium-sized customers. A network of national and regional distributors is employed, as well as our own sales force, to reach customers using POC diagnostic tests.

We have expanded the size of our North America sales force in the past few years. As of December 31, 2020, we employed approximately 120 sales representatives in North America. This sales force works closely with our key distributors to drive market penetration of our products in the POC market.

The sales, distribution and service of our cell culture tests are controlled primarily by us. Laboratory end-users in hospitals and clinical reference laboratories using these diagnostic tests are reached through our own direct sales force and technical support services that have specialized training and understanding of the product portfolio.

We sell products globally and market and distribute products in a variety of ways, including a mix of direct and distribution strategies worldwide. In Europe, we currently employ approximately 85 employees to support sales and marketing activities in key countries, such as Germany and Italy. In addition, we have created a shared service center in Galway, Ireland to support general and administrative, technical support and customer service functions in Europe. In Asia, we currently employ approximately 50 employees in China and approximately 20 employees in India, primarily to support sales and marketing efforts for the Triage and BNP Businesses and to grow our core immunoassay and cell culture businesses. In addition, we have created a shared service center in Shanghai, China to support general and administrative and technical support and customer service functions in China.

We derive a significant portion of our total revenue from a few distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 68%, 51% and 49% of our total revenue for the years ended December 31, 2020, 2019 and 2018, respectively. See Note 9 in the Consolidated Financial Statements included in this Annual Report.

Manufacturing

We have three primary manufacturing sites. Two are in San Diego, California and one is located in Athens, Ohio. In addition, we are building out an additional manufacturing site in Carlsbad, California, which is expected to begin operations in the second half of 2021.

Our McKellar Court lateral flow manufacturing facility is located in San Diego, California and consists of laboratories devoted to tissue culture, cell culture, protein purification and immunochemistry. Production areas are dedicated to manufacturing and assembly. In the manufacturing process, biological and chemical supplies and equipment are used. We have invested in a high degree of automated equipment for the assembly and inspection processes. Since 2000, this facility has operated under a Quality Management System certified to International Organization for Standardization ("ISO") standard. The facility is certified to ISO 13485:2016 and Medical Device Single Audit Program ("MDSAP") medical device standards. Many of the immunoassay products manufactured in this San Diego facility are packaged and shipped by a local third party.

Our Athens facility consists of a variety of laboratories, clean rooms and customized filling and packaging areas to support manufacturing of all products under Good Manufacturing Practice (GMP) conditions. These areas support the manufacturing of our molecular nucleic acid amplification products, our living tissue culture and antibody- based products, as well as our enzyme linked immunosorbent assays. We use a wide variety of biological and chemical supplies in our manufacturing processes. We also utilize specialized equipment for the lyophilization of reagents, cell culture growth, protein purification and a variety of automation for dispensing of antibodies, reagents and solutions. The facility is certified to ISO

13485:2016 and MDSAP medical device standards. Packaging, warehousing and shipping logistics with cold chain storage capability are handled at the facility.

Our Summers Ridge, San Diego, California facility consists of laboratories that are involved in mammalian cell culture, bacterial fermentation, protein purification and modification, as well as other techniques involved in immunoassay reagent manufacturing. These reagents are used in the manufacture of devices made at the site and are also supplied to a third party as key active ingredients for our BNP product that is run on the Beckman Coulter Immunoassay Systems. In addition, this site has production areas dedicated to creating and processing plastic components that are subsequently transformed into finished devices (Cardiac and Drugs of Abuse products) using customized manufacturing equipment, including specialized automation. This facility is certified to the EN ISO 13485:2016 and MDSAP medical device standards. Most of the products are packaged and subsequently distributed out of the facility.

We seek to conduct our manufacturing in compliance with regulations that comply to U.S., Australia, Brazil, Canada, Japan, Europe, South Korea and other countries Quality Management System ("QSR") requirements. Our manufacturing facilities have passed routine regulatory inspections confirming compliance with the QSR regulatory requirements. Our facilities are registered with various regulatory bodies including the FDA and the Department of Health Services of the State of California for our San Diego facilities.

Government Regulation

Regulation in the United States

The testing, manufacture and commercialization of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Pursuant to the U.S. Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other matters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant premarket clearance or premarket approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution. The FDA also has the authority to request a recall, repair, replacement or refund of the cost of any device manufactured or distributed in the U.S. if the device is deemed to be unsafe.

In the U.S., devices are classified into one of three classes (Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. Class I and II devices are subject to general controls including, but not limited to, performance standards, premarket notification ("510(k)") and post market surveillance. Class III devices generally pose the highest risk to the patient and are typically subject to premarket approval to ensure their safety and effectiveness. Our current products are all Class I or II.

The FDA can authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product, referred to as Emergency Use Authorization, or EUA, for certain emergency circumstances after the Health and Human Services Secretary has made a declaration of emergency justifying authorization of emergency use. An EUA allows use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by emerging infectious disease threats when there are no adequate, approved, and available alternatives. The FDA may also waive otherwise-applicable current good manufacturing practice (CGMP) requirements to accommodate emergency response needs. All of our current products for testing for the COVID-19 virus are sold under EUA.

Prior to commercialization in the U.S. market, manufacturers of diagnostic assays like our products are typically required to obtain FDA clearance through a premarket notification or premarket approval process, which can be lengthy, expensive and uncertain. The FDA has been requiring more rigorous demonstration of product performance as part of the 510(k) process, including submission of extensive clinical data. It generally takes from three months to one year to obtain clearance but may take longer. A premarket approval application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of clinical investigations, bench tests and reference laboratory studies. In addition, modifications or enhancements for existing products that could significantly affect safety, effectiveness or constitute a major change in the intended use of the device, will require new submissions to the FDA.

CLIA regulates laboratory testing and require clinical laboratories to be certified by their state as well as the Center for Medicare and Medicaid Services (CMS) before diagnostic testing can be conducted. Labs using our assays must obtain a CLIA certificate. Waived testing is designated by CLIA as simple testing that carries a low risk for an incorrect result. The CLIA waived designation is critical for most of our products that are intended for POC settings. The FDA's current guidance entitled "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 CLIA

Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" sets forth requirements for obtaining a CLIA waiver that are onerous and have increased the time and cost required to obtain a CLIA waiver.

Any devices we manufacture or distribute pursuant to FDA clearance or approvals are subject to continuing regulation by the FDA and certain state agencies, including adherence to QSR relating to testing, control, documentation and other quality assurance requirements. We must also comply with Medical Device Reporting requirements mandating reporting to the FDA of any incident in which a device may have caused or contributed to a death or serious injury, or in which a device malfunctioned and, if the malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

Regulation Outside of the United States

For marketing outside the U.S., we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the U.S., and may require us to perform additional or different preclinical or clinical testing regardless of whether we have obtained FDA clearance or approval. The amount of time required to obtain necessary approvals may be longer or shorter than that required for FDA clearance or approval. In many foreign countries, pricing and reimbursement approvals are also required.

Our initial focus for obtaining marketing approval outside the U.S. is typically the European Union (EU), Japan, China, Brazil, Australia and Canada. EU regulations and directives generally classify healthcare products either as medicinal products, medical devices or *in vitro* diagnostics. The CE Mark certification for the EU requires us to receive certification for the manufacture of our products from ISO. This certification comes only after the development of an all-inclusive quality system, which is reviewed for compliance with ISO standards by a notified body accredited by an EU member state. After certification is received, a technical file is developed which attests to the product's compliance to Regulation Directive 98/79/EC for *in vitro* diagnostic medical devices. Only after this point is the product CE marked. In addition, the EU has recently adopted the EU Medical Device Regulation (the "EU MDR") and the In Vitro Diagnostic Regulation (the "EU IVDR"), each of which impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Manufacturers of currently approved medical devices will have until May 2021 to meet the requirements of the EU MDR and until May 2022 to meet the EU IVDR. Complying with the requirements of these regulations may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

Chinese regulations require registration of diagnostic products with China's National Medical Products Administration (NMPA, formerly CFDA). Additional clinical trials in China are typically required for registration purposes. ISO certification is included in applications for registration to NMPA. Japanese regulations require registration of *in vitro* diagnostic products with the Japanese Ministry of Health, Labor and Welfare. For products marketed in Canada, registration is required with Health Canada. For products marketed in Australia, registration is required with the Therapeutic Goods Administration. In vitro diagnostics in Brazil are regulated by the Agencia Nacional de Vigilancia Sanitaria (ANVISA). For our products marketed in Canada, Japan, Brazil, Australia and the United States, the MDSAP is a single regulatory audit of our quality management system that satisfies the requirements of all five of these jurisdictions. Additionally, with Brexit in place, we are obtaining any necessary approvals directly with the U.K.'s Medicines and Healthcare Products Regulatory Agency.

Intellectual Property

The healthcare industry has traditionally placed considerable importance on obtaining and maintaining patent and trade secret protection for commercially relevant technologies, devices, products and processes. We and other companies engaged in research and development of new diagnostic products actively seek to protect trade secrets and pursue patents for technologies that are considered novel and patentable. However, important factors, many of which are not within our control, can affect whether and to what extent patent protection in the U.S. and in other important markets worldwide is obtained. By way of example, the speed, accuracy and consistency in application of the law in a patent office within any particular jurisdiction is beyond our control and can be unpredictable. The resolution of issues such as these and their effect upon our long-term success is likewise indeterminable. We have issued patents, both in the U.S. and internationally, and have patent applications pending throughout the world.

It has been our policy to file for patent protection in the U.S. and other countries with significant markets, such as Western European countries and Japan, if the economics are deemed to justify such filing and our patent counsel advises that relevant patent protection may be obtained.

A large number of individuals and commercial enterprises seek patent protection for technologies, products and processes in fields in, or related to, our areas of product development. To the extent such efforts are successful, we may be required to obtain licenses and pay significant royalties in order to exploit certain of our product strategies. Licenses may not be available to us at all or, if so available, may not be available on acceptable terms.

We are aware of certain patents issued to various developers of diagnostic products with potential applicability to our diagnostic technology. We have licensed rights from companies to assist with the manufacturing of certain products. In the future, we expect that we will require or desire additional licenses from other parties in order to refine our products further and to allow us to develop, manufacture and market commercially viable or superior products effectively.

We seek to protect our trade secrets and technology by entering into confidentiality agreements with employees and third parties (such as potential licensees, customers, strategic partners and consultants). In addition, we have implemented certain security measures in our laboratories and offices. Also, to the extent that consultants or contracting parties apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data.

Under many of our contractual agreements, we have agreed to indemnify the counterparty against costs and liabilities arising out of any patent infringement claims and other intellectual property claims asserted by a third party relating to products sold under those agreements.

Competition

Competition in the development and marketing of IVD products is intense, and innovation, product development, regulatory clearance to market and commercial introduction of new IVD technologies can occur rapidly. We believe that some of the most significant competitive factors in the rapid diagnostic market include convenience, speed to result, specimen flexibility, product menu, clinical needs, price, reimbursement levels and product performance as well as effective distribution, advertising, promotion and brand name recognition. The competitive factors in the central laboratory market are also significant and include price, product performance, reimbursement, compatibility with routine specimen procurement methods, and manufacturing products in testing formats that meet the workflow demands of larger volume laboratories. We believe our success will depend on our ability to remain abreast of technological advances, to develop, gain regulatory clearance and introduce technologically advanced products, to effectively market to customers a differentiated value proposition represented by our commercialized products, to maintain our brand strength and to attract and retain experienced personnel. The majority of diagnostic tests requested by physicians and other healthcare providers are performed by independent clinical reference laboratories. We expect that these laboratories will continue to compete vigorously to maintain their dominance of the testing market. In order to achieve market acceptance for our products, we will be required to continue to demonstrate that our products provide physicians and central laboratories cost-effective and time-saving alternatives to other competitive products and technologies.

Many of our current and prospective commercial competitors, including several large pharmaceutical and diversified healthcare companies, have substantially greater financial, marketing and other resources than we have. These competitors include, among others, Abbott Laboratories, Beckman Coulter Primary Care Diagnostics, Thermo Fisher Scientific, Becton Dickinson and Company, Meridian Bioscience, Inc., and Danaher Corporation. We also face competition from our distributors since some have created, and others may decide to create, their own products to compete with ours. Competition may also exist with large, medium and small development companies whose portfolio and technologies are dedicated to the development of diagnostic solutions in areas in which we currently have relevant market share.

Seasonality

Sales of our influenza products are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons, prevalent during the fall and winter. As a result of these seasonal demands, we typically experience lower sales volume in the second and third quarters of the calendar year, and typically have higher sales in the first and fourth quarters of the calendar year. The COVID-19 pandemic and impact of sales of our COVID-19 products combined with a very mild flu season diminished the seasonal effects in 2020. Historically, sales of our influenza products have varied from year to year based in large part on the severity, length and timing of the onset of the cold and flu season. For the years ended December 31, 2020, 2019 and 2018, sales of our influenza products accounted for 8%, 26% and 24%, respectively, of total revenue. In addition, it is possible that the SARS-CoV-2 virus may have similar seasonal demands and impacts on our revenues in the future.

Human Capital Resources

As of December 31, 2020, we had approximately 1,370 employees worldwide, with approximately 1,200 employees in the United States and approximately 170 employees outside of the United States, none of whom are represented by a labor union. We have experienced no work stoppages and believe that our employee relations are good.

Our employees are one of our most important assets and set the foundation for our ability to achieve our strategic objectives, drive operational execution, deliver strong financial performance, advance innovation and maintain our quality and compliance programs.

The success and growth of our business depends in large part on our ability to attract, retain and develop a diverse population of talented and high-performing employees at all levels of our organization. To succeed in a competitive labor market, we have recruitment and retention strategies that we focus on as part of the overall management of our business, including designing our compensation and benefits programs to be competitive and align with our strategic and stockholders' interests. Some of our key employee benefits include eligibility for health insurance, vacation time, a retirement plan with an employer match, an employee assistance program, life and disability coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible spending accounts, hospital care, accident insurance, prepaid legal benefits, backup childcare, family forming benefits, homework support for students, student loan debt benefits, tuition reimbursement and a wellness program.

Information about our Executive Officers

The names, ages and positions of all executive officers are listed below, followed by a brief account of their business experience. There are no family relationships among these officers, nor any arrangements or understandings between any officer and any other person pursuant to which an officer was selected.

Douglas C. Bryant, 63, was named President, Chief Executive Officer and a member of the Board of Directors in 2009. Prior to joining us, Mr. Bryant served as Executive Vice President and Chief Operating Officer at Luminex Corporation, managing its Bioscience Group, Luminex Molecular Diagnostics (Toronto), manufacturing, R&D, technical operations, and commercial operations. From 1983 to 2007, Mr. Bryant held various worldwide commercial operations positions with Abbott Laboratories including, among others: Vice President of Abbott Vascular for Asia/Japan, Vice President of Abbott Molecular Global Commercial Operations and Vice President of Abbott Diagnostics Global Commercial Operations. Earlier in his career with Abbott, Mr. Bryant was Vice President of Diagnostic Operations in Europe, the Middle East and Africa, and Vice President of Diagnostic Operations Asia Pacific. Mr. Bryant has over 30 years of industry experience in sales and marketing, product development, manufacturing and service and support in both the diagnostics and life sciences markets. Mr. Bryant holds a B.A. in Economics from the University of California at Davis.

Randall J. Steward, 66, became our Chief Financial Officer in October 2011. Prior to joining us, Mr. Steward served as the Chief Financial Officer for Navilyst Medical, Inc., a medical device company based in Massachusetts. From 2008 to January 2011, Mr. Steward served as Chief Operating Officer for SeQual Technologies, Inc., a San Diego-based medical device company, where he was responsible for all aspects of engineering, manufacturing, finance, and information systems. Prior to SeQual Technologies, Mr. Steward spent 11 years with Spectrum Brands as Executive Vice President and Chief Financial Officer. Mr. Steward holds a B.B.A. in Accounting from Southern Methodist University. He is also a Certified Public Accountant and a member of the American Institute of Certified Public Accountants.

Robert J. Bujarski, J.D., 52, became our Chief Operating Officer in September 2020. Previously, Mr. Bujarski served as Senior Vice President, North America Commercial Operations from July 2019 to September 2020, Senior Vice President, General Counsel from August 2009 to September 2020, Senior Vice President, Business Development from August 2009 to July 2019 and General Counsel and Vice President from July 2005 to March 2007. Mr. Bujarski was an associate attorney with the law firm of Gibson, Dunn & Crutcher LLP in its transactions practice group from October 2001 to July 2005. Mr. Bujarski received his B.A. degree in 1991 and his law degree in 2001 from the University of Arizona.

William J. Ferenczy, 65, became Senior Vice President, Cardiometabolic Business Unit in April 2020. He joined Quidel in 2011 as Senior Director, US Marketing and subsequently held positions as Senior Director and General Manager, Savanna and Vice President, Strategy and Global Product Management. Mr. Ferenczy has over 30 years of experience leading product launches and market development across a wide range of diagnostic companies including Abbott Diagnostics, Biosite Diagnostics, Nanosphere and Inovise Medical. Early in his career, he held several manufacturing management positions of

increasing responsibility at Abbott Hospital Products and General Medical Manufacturing. Mr. Ferenczy holds a B.S. in Pre-professional studies from the University of Notre Dame.

Karen C. Gibson, 59, became our Senior Vice President, Digital Health Business Unit in October 2020. Ms. Gibson previously served as Senior Vice President, Information Systems and Business Transformation from February 2019 to October 2020. Ms. Gibson joined Quidel in April 2015 as Vice President, Information Systems and in 2017 took on additional responsibilities as the Integration Lead for the integration of the Triage and BNP Businesses. Prior to Quidel, Ms. Gibson was an independent executive consultant for approximately three years and previously held a variety of senior positions within the life sciences industry. She held the role of Senior Vice President and Chief Information Officer for McKesson's Specialty Health division. She also served as Senior Vice President and Chief Information Officer for Life Technologies, and as Vice President and Chief Information Officer for General Electric's Healthcare IT business unit. Ms. Gibson has an MBA from Ohio University, and B.S. in Computer Technology from Purdue University.

Michelle A. Hodges, 61, became our Senior Vice President, General Counsel in December 2020. Prior to joining Quidel, Ms. Hodges was a corporate lawyer with the law firm of Gibson, Dunn & Crutcher LLP from December 1996 through November 2020, most recently as a partner from 2005. Ms. Hodges received her B. Hort. Sci. degree from Massey University, New Zealand, and her J.D. and M.B.A. from UCLA.

Werner Kroll, Ph.D., 64, became our Senior Vice President, R&D in May 2014. Prior to joining us, Dr. Kroll was Vice President and Global Head Research and Innovation for Novartis Molecular since 2009. Prior to holding that position, he held a variety of senior positions from 2005 to 2009 at Novartis. Dr. Kroll has also held senior positions at Bayer from 1991 to 2005. Dr. Kroll received his Ph.D. and a Diploma in Chemistry from the University of Marburg.

Tamara A. Ranalli, Ph.D., 48, became the Senior Vice President, Molecular Business Unit in August 2020. Prior to this position at Quidel, she held several roles at Quidel most recently as Vice President of Marketing for North America and has been with the organization since 2010. Before joining Quidel, Dr. Ranalli was the Director of Business Development at BioHelix Corporation where she was instrumental in both the development of the novel isothermal technology used in the Solana platform as well as in establishing the collaboration between BioHelix and Quidel that led to our eventual acquisition of BioHelix in 2013. Dr. Ranalli holds a B.A. degree in Biology from Cornell University, a Ph.D. in Biochemistry from University of Rochester School of Medicine and completed a post-doctoral fellowship in Cancer Genetics at Roswell Park Cancer Institute.

Edward K. Russell, 53, became our Senior Vice President, Business Development in July 2019. Mr. Russell joined the Company in October 2015 as Senior Vice President, Global Commercial Operations and subsequently became our Senior Vice President, North America Commercial Operations. Prior to joining the Company, Mr. Russell was employed by Thermo Fisher Scientific, a life sciences company based in Massachusetts, and its predecessor company Life Technologies for ten years. Mr. Russell served in various leadership roles from 2005 through 2015, including North America Commercial Leader of the BioSciences Division, General Manager of Life Technologies' Global Services & Support Division, and President of Life Technologies Japan. Prior to joining Life Technologies in 2005, Mr. Russell held various leadership positions at FedEx Kinko's, ExxonMobil and Toyota/Lexus. Mr. Russell started his career as an officer in the U.S. Coast Guard. Mr. Russell holds a B.S. in Civil Engineering from the U.S. Coast Guard Academy and an MBA from The Wharton School, University of Pennsylvania.

Item 1A. Risk Factors

Operational and Strategic Risks

The novel coronavirus global pandemic could adversely affect our business operations, financial performance and results of operations, the extent of which is uncertain and difficult to predict.

In late 2019, a novel strain of COVID-19 was identified, which has since spread globally and evolved into a global pandemic, including severe and widespread transmission in the United States and throughout the world. In response, government authorities throughout the United States and around the world have implemented numerous measures to try to reduce the spread of COVID-19, such as travel restrictions, quarantines, shelter in place or total lock-down orders and other business restrictions. As a result of the COVID-19 outbreak and the related responses from government authorities, our business operations, financial performance and results of operations may be adversely impacted in a number of ways, including, but not limited to, the following:

- a slowdown or stoppage in the supply chain of the raw materials, components, equipment and packaging services used to manufacture our products or our inability to secure additional or alternate sources of supplies or services needed to manufacture our products at optimal levels;
- our inventory might be requisitioned, diverted or allocated by government order such as under emergency, disaster and civil defense declarations. For example, government actions in response to the COVID-19 pandemic affect our supply allocation, and those and our own allocation decisions can impact our customer relationships;
- interruptions or delays in global shipping to transport and deliver our products to our distributors and customers;
- interruptions in normal operations of certain end use customers that could result in reductions in demand for non-COVID-19 related healthcare operations and testing;
- disruptions to our operations, including a shutdown of one or more of our facilities or product lines; restrictions on our operations and sales, marketing and distribution efforts; and interruptions to our research and development, manufacturing, clinical/regulatory and other important business activities;
- increased costs in our manufacturing, production and shipping processes;
- limitations on employee resources and availability, including due to sickness or personal quarantine, government restrictions, the desire of employees to avoid contact with large groups of people, school closures or mass transit disruptions;
- an increase in cyber-attacks given our increased public profile, particularly as a manufacturer of COVID-19 products;
- a fluctuation in foreign currency exchange rates or interest rates could result from market uncertainties;
- an increase in exposure to credit losses for customers adversely affected by the COVID-19 pandemic;
- an increase in regulatory restrictions or continued market volatility could hinder our ability to execute strategic business activities, including acquisitions; and
- an increase in the volatility of our stock price.

The spread of COVID-19 has caused us to modify our business practices (including employee travel, employee work locations, and physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers, partners, and suppliers. Such measures may not mitigate fully the risks posed by the virus, impairing our ability to perform critical functions.

In response to increased demand brought on by COVID-19, we are continuing to rapidly and significantly expand our manufacturing capacity, including expanding and scaling our infrastructure to support existing and anticipated COVID-19 testing demand and commercial activities. This rapid expansion has placed and may continue to place significant strain on our management, personnel, operations, systems and financial resources. Failure to successfully manage this expansion could negatively affect our operating results, including due to inefficiencies in implementing such expansion or higher costs for materials, technology, equipment and human capital during the intensity of the COVID-19 pandemic. Moreover, we may not realize the revenue growth and profitability we anticipate for our COVID-19 and other diagnostic products, which could cause, among other results, a failure to realize the benefits of our manufacturing capacity expansion and the value of those investments being written down or written off.

Additionally, COVID-19 could negatively affect our internal controls over financial reporting as a portion of our workforce is required to work from home and therefore new processes, procedures, and controls could be required to respond to

changes in our business environment. Further, should any key employees become ill from COVID-19 and unable to work, the attention of the management team could be diverted.

The effects of COVID-19 may exacerbate our other risk factors described below. The degree to which COVID-19 impacts our business operations, financial performance and results of operations will depend on future developments, which are highly uncertain, continuously evolving and cannot be predicted, including, but not limited to, the duration of the COVID-19 outbreak, the severity of continual outbreak surges, the actions to contain the virus or treat its impact, how quickly and to what extent normal economic and operating conditions can resume and the residual economic and other effects. Because this situation continues to evolve globally, the ultimate impacts to us of COVID-19 are uncertain, but such impacts could have a material adverse effect on our business, financial performance and financial condition.

The industry and market segment in which we operate are highly competitive, and intense competition with other providers of diagnostic products or services may reduce our sales and margins.

Our diagnostic tests compete with similar products made by our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diversified healthcare companies. We also face competition from our distributors as some have created, and others may decide to create, their own products to compete with ours. A number of our competitors have competitive advantages, such as substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. Our operating results could be materially and adversely affected if:

- our competitors' products are more effective than ours or take market share from our products through more effective marketing or competitive pricing;
- our competitors obtain patent protection or other intellectual property rights that prevent us from offering competing products or services; or
- our competitors are able to obtain regulatory approvals for products or services or otherwise bring competing products to market earlier than us.

In addition, there has been a trend toward industry consolidation in our markets over the last few years. We may not be able to compete successfully in an increasingly consolidated industry. We expect this trend toward industry consolidation to continue as companies attempt to strengthen or hold their market positions in an evolving industry.

In order to remain competitive and profitable, we must expend considerable resources to research new technologies and products and develop new markets, and there is no assurance our efforts to develop new technologies, products or markets will be successful or such technologies, products or markets will be commercially viable.

We devote a significant amount of financial and other resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products and new technologies require a significant investment of resources, such as new employees, offices, manufacturing facilities, and development of new commercial partners and channels. Such expenditures to develop new technologies, products or markets may not lead to commercially viable technology and products or successful markets.

Our operations will be adversely affected if our operating results do not correspondingly increase with our increased expenditures or if our technology, product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new technologies or products and develop new markets could have a material adverse effect on our business and prospects.

Our operating results are heavily dependent on sales of our COVID-19 and influenza diagnostic tests and if sales or revenues of our COVID-19 or influenza tests decline for any reason, our operating results would be materially and adversely affected.

A significant percentage of our total revenues come from a limited number of our product families. In particular, revenues from the sale of our COVID-19 and influenza tests represent a significant portion of our total revenues and are expected to remain so for at least the near future. For the years ended December 31, 2020, 2019 and 2018, sales of our COVID-19 products accounted for 70%, 0% and 0% and influenza products accounted for 8%, 26%, and 24%, respectively, of total revenue. In addition, the gross margins derived from sales of our COVID-19 and influenza tests are significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our COVID-19 or influenza tests decline for any reason whether as a result of an end to the COVID-19 pandemic, a mild flu season, market share loss or price pressure,

obsolescence, regulatory matters, such as loss of EUAs for our COVID-19 products, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis.

We rely on a limited number of key distributors that account for a significant portion of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales.

Although we have many distributor relationships in the U.S., the market is dominated by a small number of these distributors. Four of our U.S. distributors, collectively accounted (each individually in excess of 10%) for approximately 68%, 51%, and 49% of our total revenue for the years ended December 31, 2020, 2019 and 2018, respectively. In addition, we rely on a few key distributors for a majority of our international sales and expect to continue to do so for the foreseeable future. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives are timely found or lost sales to a distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business from a lost or terminated distributor to one or more new distributors, our business, operating results and financial condition could be materially and adversely affected.

Our results of operations and financial condition may be adversely affected by the financial soundness of our customers and suppliers.

If our customers' or suppliers' operating and financial performance deteriorates, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit to us or impose different payment terms or reduce or terminate production of products they supply to us. Any inability of customers to pay us, or any demands by suppliers for different payment terms, may adversely affect our operating results and financial condition.

We may not achieve market acceptance of our products among physicians, healthcare providers or other customers, and this would have a negative effect on future sales.

A large part of our current business is based on the sale of rapid POC diagnostic tests. Our future sales depend on, among other matters, capture of sales from central laboratories by achieving market acceptance of POC testing from physicians other healthcare providers or other customers. If we do not capture sales at the levels anticipated in our budget, our total revenue will not be at the levels that we expect and the costs we incur or have incurred may be disproportionate to our sales levels. We expect that clinical reference and hospital-based laboratories will continue to compete vigorously against our POC diagnostic products in order to maintain and expand their existing dominance of the overall diagnostic testing market. Moreover, even if we can demonstrate that our products are more cost-effective, save time, or have better performance, physicians and other healthcare providers may resist changing to POC tests. Our failure to achieve market acceptance from physicians, healthcare providers or other customers with respect to the use of our diagnostic products would have a negative effect on our future sales.

Our total revenue could be affected by third-party reimbursement policies and potential cost constraints.

The end-users of our POC products are primarily physicians and other healthcare providers. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payers, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. Use of our products would be adversely impacted if physicians and other healthcare providers do not receive adequate reimbursement for the cost of our products by their patients' third-party payers. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis. Any reduction in payments by government sponsored or private payers, as a result of budget deficits or reductions in expenditures or for reimbursement reasons, may adversely affect our earnings and cash flow.

Unexpected increases in, or inability to meet, demand for our products and services could require us to spend considerable resources to meet the demand or harm our reputation and customer relationships if we are unable to meet demand.

Our inability to meet customer demand for our products and services, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. In addition, our product manufacturing of certain product lines is concentrated in one or more of our manufacturing sites. Weather, natural disasters, public health emergencies, fires, terrorism, political change or unrest, failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. This, in turn, could have a material adverse effect on our business.

If we experience unexpected increases in the demand for our products or supply shortfalls, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing capabilities in a timely manner, our total revenue could be adversely affected. For example, in response to the demand brought on by COVID-19, we have and are continuing to rapidly and significantly expand our manufacturing capacity, which has placed and may continue to place significant strain on our management, personnel, operations and systems. Failure to increase production volumes in a cost-effective manner, lower than anticipated yields or production problems could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our business, reputation, operating results and financial condition.

Interruptions in the supply of raw materials, components, equipment and other products and services could adversely affect our operations and financial results.

We depend on third-party manufacturers and suppliers for some of our materials, components, equipment, packaging and other products and services. Some of these supplies and services are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with many of these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of quality raw materials, equipment or components and our reduced control over pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver supplies or services to us as agreed. Unexpected increases in demand for our products or supply shortfalls could require us to obtain additional supplies or services in order to manufacture products to meet the demand. Some supplies require significant ordering lead time and we may not be able to timely access sufficient supplies in the event of an unexpected increase in demand or supply shortfall, particularly those obtained from a sole supplier or a limited group of suppliers. For example, government actions in response to the COVID-19 pandemic have affected our supply allocation and could in the future result in our inventory materials being requisitioned, diverted or allocated by government order such as under emergency, disaster and civil defense declarations. In addition, we use third party packaging companies to ship our products to customers. An interruption or delays in the services provided by these third-party packaging companies could also result in a delay of shipments to customers.

Our business is also subject to risks associated with U.S. and foreign legislation, regulations and trade agreements relating to the materials we import, including quotas, duties, tariffs or taxes, and other charges or restrictions on imports, which could adversely affect our operations and our ability to import materials used in our products at current or increased levels. We cannot predict whether additional U.S. and foreign customs quotas, duties (including antidumping or countervailing duties), tariffs, taxes or other charges or restrictions, requirements as to where raw materials must be purchased, or other restrictions on our imports will be imposed in the future or adversely modified, or what effect such actions would have on our costs of operations. Future quotas, duties or tariffs may have a material adverse effect on our business, financial condition, results of operations or cash flows. Future trade agreements could also provide our competitors with an advantage over us, or increase our costs, either of which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. For example, FDA regulations and labelling requirements may make switching critical supplies difficult. The SEC also requires disclosure for public companies whose products contain conflict minerals, such as tin, tantalum, tungsten and gold, that originate from the Democratic Republic of Congo and/or adjoining countries. The implementation of these requirements has caused and will continue to cause increased costs to comply with these disclosure requirements and may inhibit our ability to source these materials. Any shortfall in our supply of raw materials, equipment or components, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our business and operating results.

Failures in our information technology and storage systems, including as a result of cyber-security breaches, could significantly disrupt our business or force us to expend excessive costs.

We utilize complex information technology systems to transmit and store information, including sensitive personal information and proprietary or confidential information, and otherwise to support our business and process. In the future, our systems my prove inadequate to our business needs and necessary upgrades may not operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies caused by our enterprise resource planning systems could adversely affect our ability to, among other matters, process orders, procure supplies, manufacture and ship products, track inventory, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

Our servers are potentially vulnerable to physical or electronic break-ins, ransomware attacks, computer viruses and similar disruptive problems. Sustained or repeated system failures that interrupt our ability to generate, maintain or access data could result in a material disruption in our operations. Furthermore, a security breach could be facilitated by ineffective protection measures, employee errors or omissions, and malfeasance. Despite our efforts to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend substantial additional resources to continue to protect against potential security breaches or to remediate problems caused by such attacks or any breach of our safeguards. In addition, a data security breach or ransomware attack could distract management or other key personnel from performing their primary operational duties. If such a breach leads to disclosure of consumer, customer, supplier, partner or employee information (including personally identifiable information or protected health information), it could harm our reputation, compel us to comply with disparate state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue.

Furthermore, foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

We face risks relating to our international sales, including inherent economic, political and regulatory risks, that could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy.

Our products are sold internationally, with the majority of our international sales to our customers in Europe and Asia-Pacific. We currently sell and market our products through direct sales, distributor organizations and sales agents. Sales to foreign customers accounted for 13%, 33% and 32% of our total revenue for the years ended December 31, 2020, 2019 and 2018, respectively. Our international operations are subject to inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our business operations and impede our international growth. These foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing product registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations;
- compliance with complex foreign and U.S. laws and regulations that apply to our international operations, including U.S. laws such as import/export limitations, the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials, could expose us or our employees to fines and criminal sanctions and damage our reputation;
- tariffs or other barriers as we continue to expand into new countries and geographic regions;
- exposure to currency exchange fluctuations against the U.S. dollar;
- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection and enforcing agreements with foreign entities;
- reduced, or lack of, protection for, and enforcement of, intellectual property rights;
- social, political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future, including as a result of acts of terrorism, health pandemics, natural disasters and disruptions in global transportation;
- increased financial accounting and reporting burdens and complexities;
- complex and potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Our international operations are governed by the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws outside the U.S. Global enforcement of anti-corruption laws has increased substantially in recent years, with more enforcement proceedings by U.S. and foreign governmental agencies and the imposition of significant fines and penalties. While we have implemented policies and procedures designed to comply with these laws, our international operations, which may involve customer relationships with foreign governments, create the risk that there may be unauthorized payments or offers of payments made by employees, consultants, sales agents or distributors. Any alleged or actual violations of these laws may subject us to government investigations, significant criminal or civil sanctions and other liabilities, and negatively affect our reputation.

During the year ended December 31, 2020, we generated approximately $119.8 million in revenue denominated in currencies other than the U.S. dollar. The major currencies to which our revenues are exposed are the Euro and the Chinese Yuan. Fluctuations in the values of the Euro, the Chinese Yuan, and other foreign currencies could have a negative impact on our business, financial condition and results of operations.

Continuing worldwide political and social uncertainty, including tariffs, trade wars or social tensions, may adversely affect our business and prospects, both domestically and internationally.

Political and social uncertainty in the U.S. and throughout the world could impair political, trade and economic relations worldwide. Changes in policy in the U.S. and other countries regarding international trade, including import and export regulation and international trade agreements, could negatively impact our business. U.S. imposed tariffs on goods imported from China and certain other countries has resulted in retaliatory tariffs by China and other countries. Additional tariffs or further retaliatory trade measures taken by China or other countries in response, could affect the demand for our products and services and could impact the supply materials we use to manufacture our products. There is also uncertainty surrounding the impact of recent U.S. elections on existing and future healthcare legislation, which could have a material adverse impact on our business.

Intellectual Property Risks

To remain competitive, we must continue to develop and obtain proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling lower priced or technologically superior products or services that compete with our products.

Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to improve upon or develop, obtain and protect proprietary technology, we may lose market share or need to reduce prices as a result of competitors selling lower priced or technologically superior products or services that compete with our products, and our operating results could be adversely affected.

Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses from others. Our ability to obtain patents and licenses, and their benefits, is uncertain.

- We have issued patents both in the U.S. and internationally in various countries including, among others, Australia, Canada, China, Japan, various European countries and South Africa. Additionally, we have patent applications pending in the U.S. and various foreign jurisdictions. These pending patent applications may not result in the issuance of any patents, or if issued, may not have priority over others' applications or may not offer meaningful protection against competitors with similar technology or may not otherwise provide commercial value. Moreover, any patents issued to us may be challenged, invalidated, found unenforceable or circumvented in the future. Third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection.
- We also license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our proprietary technology around the world, we might not be aware of an unauthorized use or might not be able to enforce the license restrictions in a cost-effective manner.
- Our current and future licenses may not be adequate for the operation of our business. In the future, we expect that we will require or desire additional licenses from other parties in order to refine our products further and to allow us to develop, manufacture and market commercially viable or superior products. We may not be able to obtain licenses for technology patented by others that is required to produce our products on commercially reasonable terms, if at all.

To protect or enforce our patent rights, it may be necessary for us to initiate patent litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits would be expensive, take significant time and could divert management's attention from other business concerns. In the event that we seek to enforce any of our patents

against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and our patent applications at risk of not being issued. If we pursue any such claim, our claims could fail or the damages or other remedies awarded to us, if any, could hold little to no economic value. Further, these lawsuits may provoke the defendants to assert claims against us, which carries further risk, described in a separate risk factor below.

In addition to our patents, we rely on confidentiality agreements and other similar arrangements with our employees and other persons who have access to our proprietary and confidential information, together with trade secrets and other common law rights, to protect our proprietary and confidential technology. These agreements and laws may not provide meaningful protection for our proprietary technology in the event of unauthorized use or disclosure of such information or in the event that our competitors independently develop technologies that are substantially equivalent or superior to ours. Moreover, the laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as those in the U.S. In the event of unauthorized use or disclosure of such information, if we encounter difficulties or are otherwise unable to effectively protect our intellectual property rights domestically or in foreign jurisdictions, our business, operating results and financial condition could be materially and adversely affected.

Intellectual property risks and third-party claims of infringement, misappropriation of proprietary rights or other claims against us could adversely affect our ability to market our products, require us to redesign our products or attempt to seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.

Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. In developing and producing new products and entering new markets, we may not be able to obtain, at reasonable cost or upon commercially reasonable terms, if at all, licenses to intellectual property of others that is alleged to be part of such new or existing products. From time to time, we have received, and may continue to receive, notices that claim we have infringed upon, misappropriated or misused other parties' proprietary rights. Moreover, we are and have been subject to litigation with parties that claim, among other matters, that we infringed their patents or other intellectual property rights.

We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. These individuals or contractors may use third-party information in connection with performing services for us or otherwise reveal this third-party information to us. For these and other reasons, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations. In addition, to the extent that individuals or contractors apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data and may result in litigation.

The defense and prosecution of patent and trade secret claims are both costly and time consuming. We or our customers may be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. An adverse determination in any of these types of disputes could prevent us from manufacturing or selling some of our products, limit or restrict the type of work that employees involved with such products may perform for us, increase our costs and expose us to significant liability.

As a general matter, our involvement in litigation or in any claims to determine proprietary rights, as may arise from time to time, could materially and adversely affect our business, financial condition and results of operations for reasons such as:

- it may of itself cause our distributors or end-users to reduce or terminate purchases of our products;
- it may consume a substantial portion of our managerial and financial resources;
- the outcome of such litigation would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to procure costly licensing arrangements from third parties or withdraw or recall such products from the market, redesign such products offered for sale or under development or restrict employees from performing work in their areas of expertise;
- governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us relating to claims of misappropriation or misuse of another party's proprietary rights;
- an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, the opposing party's attorneys' fees, and future royalty payments significantly affecting our future earnings; and

- failure to obtain a necessary license (upon commercially reasonable terms, if at all) upon an adverse outcome could prevent us from selling our current products or other products we may develop.

Even if licenses to intellectual property rights are available, they can be costly. We have entered into various licensing agreements, which largely require payments based on specified product sales and/or the achievement of specific milestones. Royalty and license expenses under these arrangements collectively totaled $2.4 million, $1.1 million and $0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

In addition to the foregoing, we may also be required to indemnify certain customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon, misappropriated or misused another person's proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages

Government and Regulatory Risks

Our COVID-19 products were approved by the FDA through an EUA and the loss of such authorization could have a material adverse impact on our business, results of operations, financial position and cash flows.

The FDA can authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Health and Human Services Secretary has made a declaration of emergency justifying authorization of emergency use. An EUA allows use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by emerging infectious disease threats when there are no adequate, approved, and available alternatives. The FDA may also waive otherwise-applicable current good manufacturing practice ("CGMP") requirements to accommodate emergency response needs. All of our current COVID-19 products for testing for the COVID-19 virus were obtained under EUAs. EUAs are only effective until the emergency declaration by the Human Services Secretary ends and EUAs can also be revised or revoked by the FDA at any time as the FDA continues to evaluate the available data concerning the efficacy and safety of the product, including with respect to whether there exists superior approved products. The loss of one or more of our EUAs for our COVID-19 products could have a material adverse effect on our business, results of operations, financial position or cash flows.

Our business and products are highly regulated by various governmental agencies. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals, clearances or authorizations, the loss of previously received approvals or other changes to existing laws and regulations that adversely impact our ability to manufacture and market our products.

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. For example, the FDA regulates most of our products, which are currently all Class I or II devices. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval, clearances or authorizations for new products in the U.S. and internationally. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. Similarly, conducting clinical studies that may be required for regulatory approvals or clearances is a complex, time-consuming and expensive process, requiring months or years to complete, and our studies are not guaranteed to generate data that demonstrate safety and effectiveness or substantial equivalence of the evaluated product.

In addition, even after we obtain necessary authorizations, clearances or approvals to market our products, the FDA and other regulatory agencies may require post-market testing and additional surveillance to monitor the performance and use of approved products or may place conditions on any product approvals that could restrict the commercial applications of those products. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory authorizations, approvals or clearances, changes in laws and regulations, the loss of previously received authorizations, approvals or clearances or the placement of limits on the manufacture, marketing and use of our products. For example, prior to our acquisition of the Triage Business, the Summers Ridge, San Diego manufacturing facility was subject to a 2012 FDA inspection that resulted in an FDA warning letter and recalls of certain Triage products and revised release specifications for certain Triage meter-based products, which will not be formally closed-out with the FDA until after a future inspection. We cannot assure you that the government will find efforts to resolve the FDA warning letter to be satisfactory. We cannot predict whether other

governments' regulatory authorities will require additional remedial or corrective actions in the future, and the issues arising out of the FDA inspection may be expanded to cover other matters.

We are also subject to the provisions of a federal law commonly known as the anti-kickback statute, and several similar state laws, which prohibit payments intended to induce physicians or others to arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs that may be used with hospitals, physicians, laboratories and other potential purchasers of medical devices, including our products.

The advertising, marketing, and labeling of medical devices is highly regulated by the FDA and Federal Trade Commission ("FTC"). Our efforts to promote our products, including via direct-to-consumer marketing or social media initiatives, could subject us to additional scrutiny of our communication of risk information, benefits or claims, by the FDA, FTC, or both.

We must also comply with numerous other laws applicable to billing and payment for healthcare services, including privacy laws. Failure to comply with these requirements may result in non-payment, refunds, exclusion from government healthcare programs and civil or criminal liabilities, any of which may have a material adverse effect on our revenues, earnings and cash flows. In addition, failure by third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our products, which may have a material adverse effect on our cash flows.

Our contracts with government entities involve future funding, compliance, and possible sanctions risks

During 2020, we significantly expanded the number and scope of contracts we entered into with government entities. These contracts involve future funding and compliance risks. These contracts, like our National Institute of Health RADx-ATP contract, are subject to risks such as lack of funding or termination and heightened legal compliance requirements, and we may not be able to meet key deliverables and milestones. These contracts might not be renewed or might be terminated for convenience with little or no prior notice. Government contracts may expose us to higher potential liability than do other types of contracts. In addition, government contracts typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting and other requirements. For example, our contracts with the U.S. government generally require us to comply with the Federal Acquisition Regulations, U.S. False Claims Act, Procurement Integrity Act, Buy American Act and Trade Agreements Act. We are subject to government audits, investigations and oversight proceedings. Government agencies routinely review and audit government contractors to determine whether they are complying with contractual and legal requirements. Implementing policies, procedures and controls relating to the accounting and recordkeeping requirements is expensive and could divert management's attention from other concerns. If we fail to comply with these requirements, or we fail an audit, we are subject to various sanctions such as monetary damages, criminal and civil penalties, termination of contracts and suspension or debarment from government contract work. These requirements complicate our business and increase our compliance burden. The failure to meet key deliverables, milestones or compliance requirements could harm our reputation and might have a materially adverse impact on our business operations and our financial position or results of operations.

If one or more of our products is claimed to be defective, we could be subject to claims of liability and harm to our reputation that could adversely affect our business.

Our business involves an inherent risk of product liability claims. Our product development and production processes are complex and could expose our products to claims of defectiveness. Alleged manufacturing and design defects could lead to recalls (either voluntary or required by the FDA or other government authorities) and could result in the removal of one or more of our products from the market. Similarly, our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis or treatment of a patient and could lead to allegations that our products have caused injury or are found to be unsuitable for their intended use. We believe the risk of a product liability claim is heightened for at-home tests that may be purchased and administered by the end user customer and not a medical professional and our communication of risk information, benefits or claims, which is highly regulated by the FTC and FDA could be alleged to be misleading or erroneous. It is possible that we will receive adverse judgments in such lawsuits, and any such adverse judgments could be material. A defect or claim of a defect in the design or manufacture of our products could also have a material adverse effect on our reputation in the industry. Moreover, any product liability or other claim brought against us, regardless of merit, could be costly to defend.

We use hazardous materials in our business that may result in substantial claims against us relating to handling, storage or disposal.

We are subject to other substantial regulation relating to environmental, health and safety matters, including occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. Compliance with such laws and regulations requires significant effort and costs. For example, our research and development and manufacturing activities involve the controlled use of hazardous materials that may be subject to federal statutes commonly known as the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), Resource Conservation and Recovery Act ("RCRA"), and the Clean Water Act, among other laws and regulations. In addition, if any governmental authorities impose new regulations with additional compliance burdens or alter their interpretation of the requirements of such existing regulations, such regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs, restrictions or compliance procedures on our business or operations.

Given the nature of the penalties provided for in some of these regulations, we could be required to pay sizable fines, penalties or damages in the event of noncompliance with laws. Any violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. Further, accidental contamination or injury from these hazardous materials could lead to exposure of these materials to individuals, which could result in substantial fines, penalties or damages that are not covered by insurance

Risks Related to Our Acquisitions

If we are not able to manage our growth strategy or if we experience difficulties identifying or integrating companies or technologies we may acquire, our operating results may be adversely affected.

Our business strategy contemplates further growth, which we expect to result in expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a relatively small executive team, acquisitions and other future growth may divert management's attention from other aspects of our business and place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs. Some of our growth is expected to come from acquisitions of businesses and technologies. However, we cannot be certain that we will be able to successfully identify and acquire attractive targets.

Other risks associated with acquiring other technologies or businesses, include:

- we may not realize our anticipated benefits and cost savings within our expected time frame, or at all, or may experience unexpected costs and expenditures;
- difficulties transitioning and integrating the operations of companies or technologies that we acquire with our own operations, including difficulties integrating personnel, information systems, and internal control systems;
- adverse effects on our existing business relationships;
- potential loss of management and other key employees of the acquired businesses and inability to attract new employees;
- potential litigation arising from the acquired business's operations;
- potential contractual, regulatory, compliance, intellectual property or employment issues;
- increased exposure to international operations and sales, including fluctuations in foreign currency; and other economic, political and regulatory risks;
- write-downs of goodwill, intangible assets or other assets associated with the acquisitions; and
- inability to obtain financing for acquisitions on satisfactory terms, or at all.

We can give no assurance that we will be able to successfully identify, complete and integrate strategic acquisitions. Should we encounter difficulties in managing these tasks and risks, our growth strategy may suffer and our revenue, profitability and financial condition could be adversely affected.

Our acquisition of Alere's Triage® and BNP Businesses presents certain risks to our business and operations

On October 6, 2017, we acquired the Triage and BNP Businesses from Alere. The acquisition of these businesses presents the risk that the deferred consideration payable to Alere for the BNP Business will be payable even if BNP sales are significantly reduced, or even terminate, whether as a result of the introduction of a competing product, a determination that

provisions of the contractual arrangement with Beckman are unenforceable or otherwise. Relatedly, as further described in Note 8 to the Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report, Beckman Coulter, Inc. ("Beckman") filed a lawsuit against us in November 2017. The lawsuit relates to a contractual arrangement with Beckman we acquired in October 2017 as part of the BNP Business for the supply of antibodies and other inputs related to, and distribution of, the Triage® BNP Test for the Beckman Coulter Access Family of Immunoassay Systems. The outcome of such lawsuit may affect the value of the assets and liabilities we acquired and expose us to monetary liability. If this lawsuit is resolved against us, we may be liable for significant damages and restraints on our business, which could adversely affect our results of operations and financial condition.

Corporate Finance Risks

We may need to raise additional funds to finance our future capital or operating needs, which could have adverse consequences on our operations and the interests of our stockholders.

We may need to seek to raise funds through the issuance of public or private debt or the sale of equity to achieve our business strategy. In addition, we may need debt or equity financing to complete acquisitions. If we raise funds or acquire other technologies or businesses through issuance of equity, this could dilute the interests of our stockholders. Such financing activities may also depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when we cannot otherwise raise additional capital or issue additional debt on acceptable terms, if at all.

Additional indebtedness could be costly or have adverse consequences, such as:

- requiring us to dedicate a substantial portion of our cash flows from operations to payments on our debt;
- limiting our ability to obtain future financing for working capital, capital expenditures, acquisitions, debt obligations and other general corporate requirements;
- making us more vulnerable to adverse conditions in the general economy or our industry and to fluctuations in our operating results, including affecting our ability to comply with and maintain any financial tests and ratios required under our indebtedness;
- limiting our flexibility to engage in certain transactions or to plan for, or react to, changes in our business and the diagnostics industry;
- putting us at a disadvantage compared to competitors that have less relative and/or less restrictive debt; and
- subjecting us to additional restrictive financial and other covenants.

If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on existing indebtedness and our creditworthiness generally. Our business may not continue to generate cash flow from operations in the future sufficient to service or repay our debt. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Our debt, deferred and contingent payment obligations could materially adversely affect our financial condition and results of operations.

We have a $175.0 million Revolving Credit Facility as described in Note 3 to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report, and may incur other indebtedness from time to time. We currently have no borrowings under the Revolving Credit Facility, but we will continue to have the ability to borrow under the facility. We also have significant deferred and contingent payment obligations for the BNP Business acquisition as described in Note 10 to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report. In addition to our Revolving Credit Facility, we will continue to have the ability to incur additional debt.

The degree to which we are leveraged and are subject to deferred and contingent payment obligations could have important or materially adverse consequences to our business and operating results, including:

- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions and general corporate purposes may be impaired;
- the payment of our deferred and contingent payment obligations reduces the funds available to us for our operations and other strategic objectives;

- our debt agreements contain, and any agreements to refinance our debt likely will contain, financial and other restrictive covenants, and our failure to comply with them may result in an event of default, which, if not cured or waived, could have a material adverse effect on us;
- our level of indebtedness and deferred and contingent payment obligations may increase our vulnerability to, and reduce our flexibility to respond to, general economic downturns and adverse industry and business conditions;
- to the extent the debt we incur requires collateral to secure such indebtedness, our assets could be at risk and our flexibility related to such assets could be limited;
- our debt service and deferred and contingent payment obligations could limit our flexibility in planning for, or reacting to, changes in our business and industry;
- any borrowings under our Revolving Credit Facility will be at variable rates of interest, which may result in higher interest expense in the event of market interest rates; and
- any default under our Revolving Credit Facility may result in proceedings against collateral we have used to secure such borrowings, including substantially all of our and our guarantor subsidiaries' assets.

General Risk Factors

Our business could be negatively affected by the loss of or the inability to hire key personnel.

Our future success depends in part on our ability to retain our key personnel, including manufacturing, research and development, technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and where our operations are located. Further, we expect to grow our operations, and our needs for additional management and other key personnel are expected to increase. If we fail to retain existing key personnel, or timely identify and hire replacement or additional qualified personnel to meet expected growth, such failure could adversely impact our business. In addition, the loss of any of our key personnel, particularly key manufacturing, research and development and technical personnel, could harm our business and prospects and could impede the achievement of our research and development, operations or strategic objectives.

We are subject to, and may in the future become subject to, claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us.

From time to time, we are involved in litigation and other proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to our business. Litigation related to our company, our business, and our operations or financial performance may also involve customers, competitors, suppliers, patients, shareholders, governmental authorities or other third parties. Litigation can be lengthy, expensive and disruptive to our operations, and results cannot be predicted with certainty. An adverse decision could result in significant settlement amounts, monetary damages, fines or injunctive relief that could affect our financial condition or results of operations. Even if lawsuits do not result in an unfavorable outcome, the costs of defending or prosecuting such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert management's attention from the operation of our business, which could adversely affect our business and results of operations.

Furthermore, in the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators disagree with the manner in which we have sought to comply with applicable laws and regulations, we could be subjected to substantial civil and criminal penalties, as well as field corrective actions, product recalls, seizures or injunctions with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and affect our operating results, and any limitation on our ability to manufacture and market our products could also have a material adverse effect on our business.

We are exposed to business risk which, if not covered by insurance, could have an adverse effect on our results of operations.

We face a number of business risks, including exposure to product liability claims. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance. For example, there is a risk that product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect or may not be renewed at all. Further, we do not currently have insurance against many environmental risks we confront in our business. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters, cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations.

Changes in our tax rates or exposure to additional income tax liabilities or assessments could affect our profitability.

We are subject to income taxes in the U.S. and in various non-U.S. jurisdictions. In addition, the amount of income taxes we pay is subject to ongoing audits by U.S. federal, state and local tax authorities and by non-U.S. tax authorities. Due to the potential for changes to tax laws (or changes to the interpretation thereof) and the ambiguity of tax laws, the subjectivity of factual interpretations, the complexity of our foreign operations and intercompany arrangements and other factors, our estimates of income tax assets or liabilities may differ from actual payments, assessments or receipts. If these audits result in payments or assessments different from our reserves, our future results may include unfavorable adjustments to our tax liabilities and our financial statements could be adversely affected. If we determine to repatriate earnings from foreign jurisdictions that have been considered permanently re-invested under existing accounting standards, it could also increase our effective tax rate. In addition, any significant change to the tax system in the United States or in other jurisdictions (including changes in the taxation of international income as further described below) could adversely affect our financial statements.

Some provisions of our charter documents and Delaware law may make takeover attempts difficult, which could depress the price of our stock and inhibit our stockholders' ability to receive a premium price for their shares.

Provisions of our amended and restated certificate of incorporation could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our amended and restated certificate of incorporation allows our Board of Directors to issue up to five million shares of preferred stock and to fix the rights and preferences of such shares without stockholder approval. Any such issuance could make it more difficult for a third party to acquire our business and may adversely affect the rights of our stockholders. Our amended and restated bylaws include advance notice requirements for stockholder proposals that require stockholders to give written notice of any proposal or director nomination to us within a specified period of time prior to any stockholder meeting and do not permit stockholders to call a special meeting of the stockholders, unless such stockholders hold at least 50% of our stock entitled to vote at the meeting. We are also subject to anti-takeover provisions under Delaware law. These provisions may delay, deter or prevent a change in control of us, adversely affecting the market price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At December 31, 2020, we occupied the indicated square footage in the leased and owned facilities described below:

Location	Status	Lease term	Square Footage	Primary Use
San Diego, CA (Summers Ridge)	Leased (1)	2033 - options to extend for two additional 5-year periods	246,000	Administrative offices, sales and marketing, research and development and manufacturing (principal executive offices)
Carlsbad, CA (Rutherford)	Leased (2)	2036 - options to extend for two additional 5-year periods	128,000	Manufacturing
San Diego, CA (Waples Ct.)	Leased	2031 - options to extend for two additional 5-year periods	106,000	Office, light manufacturing, storage, packaging, assembly and distribution
San Diego, CA (McKellar)	Leased	2030 - options to extend for two additional 5-year periods	78,000	Administrative offices, research and development and manufacturing
San Diego, CA (High Bluff)	Leased	2022 - options to extend for two additional 5-year periods	30,000	This office facility was vacated in 2019 and sublet to a third party in 2020
Athens, OH	Leased	2022 - option to extend for one additional 5-year period	111,000	Administrative offices, sales and marketing, research and development and manufacturing
Beverly, MA	Leased	2023 - option to extend for one additional 3-year period	9,700	Administrative offices, research and development and manufacturing
Shanghai, China	Leased	2024 - option to extend for one additional 2-year period	8,500	Administrative offices, sales and marketing
Galway, Ireland	Leased	2028	3,900	Administrative offices, sales and marketing

(1) The Summers Ridge lease is subject to certain must-take provisions related to one additional building, consisting of approximately 71,000 square feet. See Note 8 in the Consolidated Financial Statements included in this Annual Report.

(2) The Rutherford lease agreement was executed on January 14, 2021.

We believe that our facilities are adequate for our current needs, and we currently do not anticipate any material difficulty in renewing any of our leases as they expire or securing additional or replacement facilities, in each case, on commercially reasonable terms. However, in anticipation of our growth strategy, we may pursue additional facilities.

Item 3. Legal Proceedings

The information set forth in "Litigation and Other Legal Proceedings" in Note 8 in the Consolidated Financial Statements included in this Annual Report is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the Nasdaq Global Market under the symbol "QDEL."

As of February 5, 2021, we had approximately 276 common stockholders of record and we do not anticipate paying any cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 2020:

Period	Total number of shares purchased (1)	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs (2)
September 28, 2020 - October 25, 2020	1,249	$ 214.00	—	$ 156,313,465
October 26, 2020 - November 22, 2020	1,905	187.28	—	156,313,465
November 23, 2020 - January 3, 2021	173	189.50	—	156,313,465
Total	3,327	$ 197.43	—	$ 156,313,465

(1) Includes shares surrendered, if any, to the Company to satisfy the payment of minimum tax withholding obligations and/or option exercise price obligations in connection with stock swap option exercise transactions.

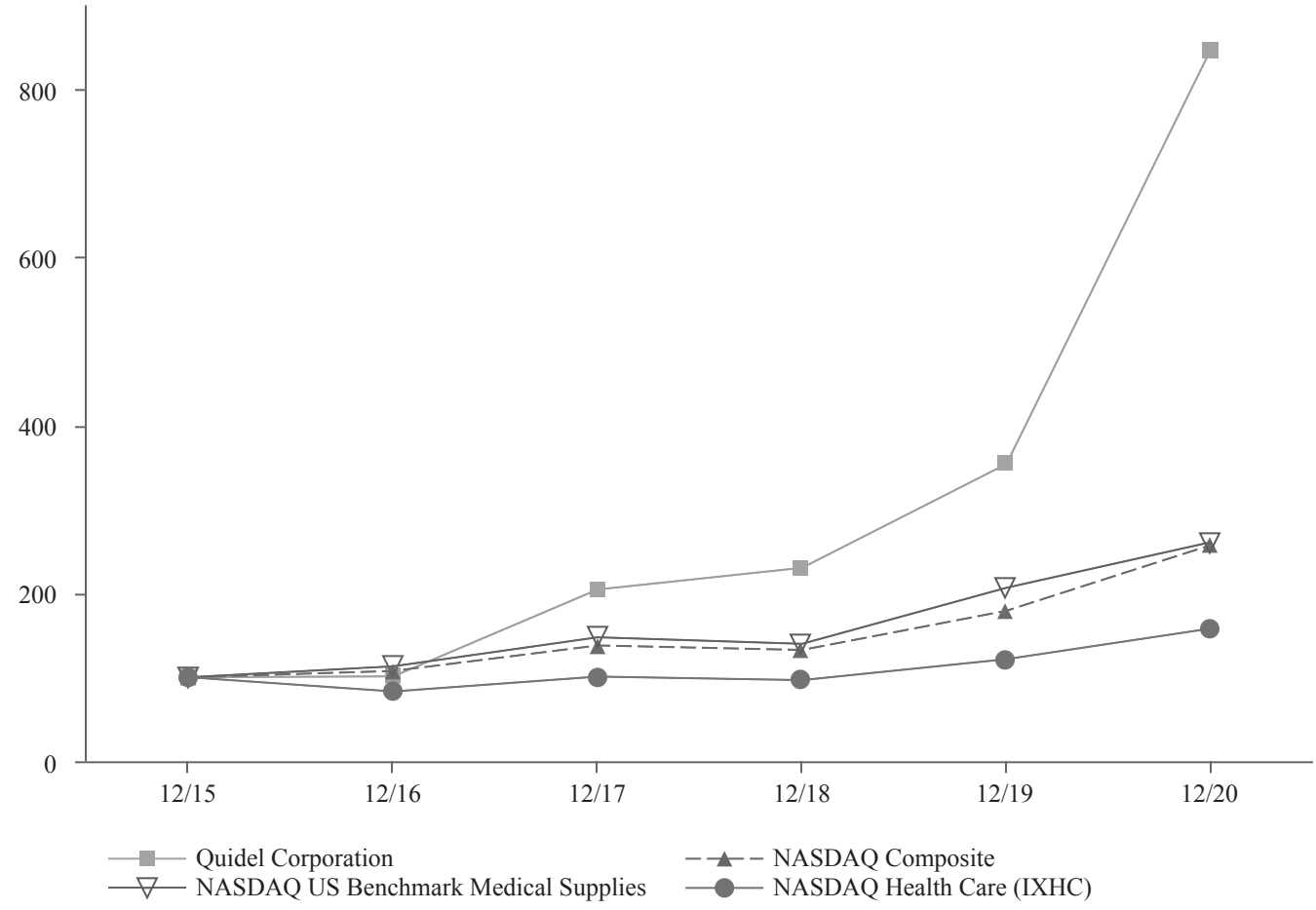
(2) On December 18, 2018, the Company announced a stock repurchase program to repurchase up to $50.0 million of the Company's shares of common stock, which was authorized by the Board of Directors (the "Board") on December 12, 2018. On August 28, 2020, the Board authorized an increase of an additional $150.0 million to the Company's existing stock repurchase program authorization, which was announced on September 1, 2020. The Board also extended the repurchase authorization through August 28, 2022.

STOCKHOLDER RETURN PERFORMANCE GRAPH

Set forth below is a line graph comparing the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index, Nasdaq Health Care Index, and Nasdaq US Benchmark Medical Supplies Index for the period beginning December 31, 2015 and ending December 31, 2020. The graph assumes (i) an initial investment of $100 on December 31, 2015 in our common stock, the Nasdaq Composite Index, the Nasdaq US Benchmark Medical Supplies Index, and the Nasdaq Health Care Index and (ii) reinvestment of dividends. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.

COMPARISON OF 5 YEAR TOTAL CUMULATIVE RETURN

Among Quidel Corporation, the NASDAQ Composite, NASDAQ US Benchmark Medical Supplies and NASDAQ Health Care Indices



Company/Index	Base Period 12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020
Quidel Corporation	**$ 100.00**	$ 101.04	$ 204.48	$ 230.28	$ 353.92	$ 847.41
NASDAQ Composite	**$ 100.00**	$ 107.50	$ 137.86	$ 132.51	$ 179.19	$ 257.38
NASDAQ US Benchmark Medical Supplies	**$ 100.00**	$ 113.04	$ 147.56	$ 139.80	$ 206.56	$ 260.84
NASDAQ Health Care	**$ 100.00**	$ 83.09	$ 100.79	$ 96.59	$ 121.54	$ 158.04

Item 6. Selected Financial Data

The following table presents selected consolidated financial data of Quidel Corporation. This historical data should be read in conjunction with the Consolidated Financial Statements and related Notes thereto included in this Annual Report and "Management's Discussion and Analysis of Financial Condition and Results of Operation" in Item 7 in this Annual Report.

Consolidated Statements of Operations

	Year ended December 31,				
	2020	2019	2018	2017 (1)	2016 (1)
	(in thousands, except per share data)				
Total revenues	$1,661,668	$ 534,890	$ 522,285	$ 277,743	$ 191,603
Cost of sales	312,813	214,085	206,572	121,601	79,872
Gross profit	1,348,855	320,805	315,713	156,142	111,731
Research and development	84,292	52,553	51,649	33,644	38,672
Sales and marketing	133,957	111,114	108,987	67,248	50,436
General and administrative	66,586	52,755	44,951	29,192	26,351
Acquisition and integration costs	3,694	11,667	14,197	16,506	711
Total operating expenses	288,529	228,089	219,784	146,590	116,170
Operating income	1,060,326	92,716	95,929	9,552	(4,439)
Other expense, net					
Interest expense, net	(9,623)	(14,790)	(24,283)	(17,588)	(12,181)
Loss (gain) on extinguishment of debt	(10,384)	(748)	(8,262)	—	421
Total other expense, net	(20,007)	(15,538)	(32,545)	(17,588)	(11,760)
Income (loss) before income taxes	1,040,319	77,178	63,384	(8,036)	(16,199)
Provision (benefit) for income taxes	230,032	4,257	(10,799)	129	(2,391)
Net income (loss)	$ 810,287	$ 72,921	$ 74,183	$ (8,165)	$ (13,808)
Basic earnings (loss) per share	$ 19.24	$ 1.78	$ 1.95	$ (0.24)	$ (0.42)
Diluted earnings (loss) per share	$ 18.60	$ 1.73	$ 1.86	$ (0.24)	$ (0.42)
Shares used in basic per share calculation	42,124	40,860	37,995	33,734	32,708
Shares used in diluted per share calculation	43,591	43,111	42,554	33,734	32,708

Balance Sheet Data

	December 31,				
	2020	2019	2018	2017 (1)	2016 (1)
	(in thousands)				
Cash and cash equivalents	$ 489,941	$ 52,775	$ 43,695	$ 36,086	$ 169,508
Working capital	$ 805,441	$ 96,336	$ 33,662	$ 202,881	$ 191,782
Total assets	$ 1,871,164	$ 910,867	$ 806,371	$ 935,251	$ 388,250
Long-term debt and finance lease obligations, net of current portions	$ 4,100	$ 4,375	$ 56,865	$ 381,110	$ 148,319
Stockholders' equity	$ 1,332,703	$ 559,820	$ 425,584	$ 227,104	$ 200,630
Common shares outstanding	42,290	41,868	39,386	34,540	32,897

(1) Includes the results of operations of the Immutopics, Inc., RPS Diagnostics and Triage and BNP Businesses, from dates of acquisition, March 18, 2016, May 16, 2017 and October 6, 2017, respectively.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of the federal securities laws that involve material risks and uncertainties. This discussion should be read in conjunction with "A Warning About Forward-Looking Statements" on page 3 and "Risk Factors" in this Annual Report. In addition, our discussion of the financial condition and results of operations of Quidel Corporation in this Item 7 should be read in conjunction with our Consolidated Financial Statements and the related Notes included elsewhere in this Annual Report. Discussions of year-to-year comparisons between 2019 and 2018 that are not included in this Annual Report can be found in our Annual Report for the year ended December 31, 2019.

Overview and Executive Summary

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions we separate into our four product categories: rapid immunoassay, Cardiometabolic immunoassay, molecular diagnostic solutions and specialized diagnostic solutions. We currently sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products through a network of distributors and through a direct sales force. We operate in one business segment that develops, manufactures and markets our four product categories.

For the year ended December 31, 2020, total revenue increased 211% to $1,661.7 million as compared to the year ended December 31, 2019, and currency exchange rates had a minimal impact on the growth rate. Our revenues can be highly concentrated over a small number of products. For the year ended December 31, 2020, sales of our COVID-19 products accounted for 70% of total revenue. For the years ended December 31, 2020, 2019 and 2018, sales of our influenza products, as a percentage of total revenue, accounted for 8%, 26%, and 24% respectively. Additionally, a significant portion of our total revenue is from a relatively small number of distributors. Approximately 68%, 51% and 49% of our total revenue for the years ended December 31, 2020, 2019 and 2018, respectively, were related to sales through our four largest distributors.

Our primary mission is to advance diagnostics to improve human health. Our strategy is to target market segments that represent significant total market opportunities, and in which we can be successful by applying our expertise and know-how to develop differentiated technologies and products.

Our diagnostic testing solutions are designed to provide specialized results that serve a broad range of customers, by addressing the market requirements of ease of use, reduced cost, increased test accuracy and reduced time to result. Our current approach is to offer products in the following product categories:

- rapid immunoassay tests for use in physician offices, hospital laboratories and emergency departments, retail clinics, eye health settings, pharmacies, other urgent care or alternative site settings to include over the counter commencing in 2021;
- cardiometabolic immunoassay tests for use in physician offices, hospital laboratories and emergency departments, and other urgent care or alternative site settings;
- molecular diagnostic tests for use in hospitals, moderately complex physician offices, laboratories and other settings; and
- specialized diagnostic solutions, including direct DFA and culture-based tests for the clinical virology laboratory and other products serving the bone health, autoimmune and complement research communities.

In order to achieve our mission, our strategy is to do the following:

- focus on innovative products and markets and leverage our core competency in new product development for our QuickVue®, Sofia® and Triage® immunoassay brands and next-generation products;
- leverage our manufacturing expertise to address increasing demand for our products, including through expanded manufacturing capacity;
- utilize our molecular assay development competencies to further develop our molecular diagnostics franchise that includes distinct testing platforms, such as Lyra®, Solana® and Savanna®; and
- strengthen our position with distribution partners and our end-user customers to gain more emphasis on our products and enter new markets.

Our current initiatives to execute this strategy include the following:

- provide products that can compete effectively in the healthcare market where cost and quality are important;
- focus our research and development efforts on three areas:
  - new proprietary product platform development;
  - the creation of new and improved products for use on our established platforms to address unmet clinical needs, and
  - pursuit of collaborations with, or acquisitions of, other companies for new and existing products and markets that advance our differentiated strategy;
- leverage our international infrastructure and enhance our global footprint to support our international operations and future growth;
- strengthen our market and brand leadership in current markets by acquiring and/or developing and introducing clinically superior diagnostic solutions;
- strengthen our direct sales force to enhance relationships with integrated delivery networks, laboratories and hospitals, with a goal of driving growth through improved physician and laboratorian satisfaction;
- leverage our wireless connectivity and data management systems, including cloud-based tools;
- support payer evaluation of diagnostic tests and establishment of favorable reimbursement rates;
- provide clinicians with validated studies that encompass the clinical efficacy and economic efficiency of our diagnostic tests for the professional market;
- pursue alternative markets for point-of-care diagnostics;
- create strong global alliances to support our efforts to achieve leadership in key markets and expand our presence in emerging markets;
- further refine our manufacturing efficiencies and productivity improvements to increase profit; and
- pursue potential acquisitions to support our strategic initiatives.

Impact of COVID-19 Pandemic

Events surrounding the SARS-CoV-2 virus that emerged in late 2019 and the ensuing global pandemic has had a dramatic impact on businesses globally and our business as well. The severity and duration of the pandemic and economic repercussions of the virus and government actions in response to the pandemic remain uncertain and will ultimately depend on many factors, including the speed and effectiveness of the containment efforts throughout the world, the duration and spread of the virus as well as potential seasonality or new outbreaks.

In the United States, federal, state, and local government directives and policies have been put in place to manage public health concerns and address the economic impacts, including sharply reduced business activity, increased unemployment, and overall uncertainty presented by this new healthcare challenge. Similar actions have been taken by governments around the world. While all our sites are currently operational globally, our facilities could be required to temporarily curtail production levels or temporarily cease operations based on government mandates or as a result of the pandemic. To mitigate risks, we continue to evaluate the nature and extent COVID-19 may have to our business and operations and adjust risk mitigation planning and business continuity activities as needed.

New SARS-CoV-2 Diagnostic Products

As a leader in point-of-care diagnostics and with established expertise in respiratory infectious disease products, we are well-positioned to respond to the COVID-19 pandemic. We worked closely with national and local governments, agencies, and industry partners to develop, manufacture and supply critical diagnostic products to support testing initiatives to help curb the spread of the SARS-CoV-2 virus. In particular, we have developed new molecular and antigen products to diagnose the SARS-CoV-2 virus. We have experienced exceptional demand for such products. In response, we have committed and continue to commit significant resources toward the expansion of our production capacity.

We expect demand for our molecular and antigen assays and instruments to continue for the near-term at elevated levels, especially in the United States. At the same time, we also have observed decreased demand for certain of our other diagnostic products in connection with customers closing or decreasing their operations and/or patients deferring treatment. The extent to which COVID-19 will impact demand for our products depends on future developments, which are highly uncertain and very difficult to predict, including new information that may emerge concerning the severity of the coronavirus, impact of new SARS-CoV-2 variants and actions to contain and treat its impacts, including the vaccination programs now being implemented.

Operations and Employee Safety

While many governments have implemented lockdown and shelter-in-place orders, requiring non-essential businesses to shut down operations, our business is deemed "essential" and we have continued to operate, manufacture and distribute products to customers. We have implemented preparedness plans designed to help protect the safety of our employees and maintain operational continuity with an emphasis on manufacturing, product distribution and product development during this crisis. To date, we have been able to maintain our operations without significant interruption and have been able to develop and quickly scale manufacturing capacity for new products related to the COVID-19 pandemic.

To mitigate the pandemic's impact, we have transitioned many non-essential employees to work remotely, and have implemented preventative protocols intended to help safeguard our on-site employees and maintain business continuity in the event government restrictions or severe outbreaks impact our operations at certain sites. We have also enhanced cleaning and sanitizing procedures, provided additional personal hygiene supplies and protective equipment to personnel, implemented health screening protocols and periodic testing for essential personnel, limited access to facilities to outside persons who are not critical to continuing our operations, trained employees on guidelines for social distancing and face coverings and isolation and quarantine of personnel as we deem appropriate given the facts, circumstances and applicable laws or regulations. These measures have created additional burdens on our infrastructure and information technology systems and may result in decreased productivity and increased operating costs. However, the various responses we have put in place have to date resulted in limited disruption to our normal business operations.

Supply Chains

As a result of the COVID-19 pandemic, we have seen delays in receipts for certain raw materials and components for our products. Such delays can result in disruption to our business operations. We are continuously evaluating our supply chain to identify potential gaps and take steps intended to ensure continuity. We have considered potential political, legal or regulatory actions that could be taken as a result of the pandemic in jurisdictions where we manufacture, source or distribute products that could impact our supply of products to our customers or the availability of raw materials and components from our suppliers. We cannot currently predict the frequency, duration or scope of these government actions and any supply disruptions, and the availability of various products is dependent on our suppliers, their location and the extent to which they are impacted by the COVID-19 pandemic, among other factors. We are proactively working with manufacturers, industry partners and government agencies to help meet the needs of our customers during the pandemic.

Our inventory levels continue to fluctuate due to supply chain constraints in conjunction with larger and more frequent customer orders. In response, we have added alternate suppliers for certain critical components and instruments, increased inventory of raw materials needed in our operations, increased manufacturing capacity and continue to explore opportunities for further expansion in our Athens, Ohio and San Diego, California facilities. In January 2021, we significantly expanded our capacity by entering into a long-term lease for an additional manufacturing facility in Carlsbad, California. This facility is expected to begin operations in the second half of 2021.

We are seeking to minimize the impact of delays and secure allocations of vital raw materials to meet extremely high demand for our products. However, dependent on the duration and continued intensity of the current pandemic, we may experience some sort of interruption to our supply chains, and such an interruption could materially affect our ability to timely manufacture and distribute our products and unfavorably impact our results of operations depending on the nature and duration of such interruption.

Outlook

We anticipate continued revenue growth over the next year, including increased sales of testing products related to the COVID-19 pandemic, with a positive impact on gross margin and earnings. We expect to continue to invest heavily in research and development activities for our next generation immunoassay and molecular platforms as well as additional assays to be launched on our current platforms, with the most recent focus on assays to address the COVID-19 pandemic. Additionally, we are making substantial investments in the expansion of our production capacity in response to the demand driven by the COVID-19 pandemic. We intend to continue our focus on prudently managing our business and delivering improved financial results, while at the same time striving to introduce new products into the market and maintain our emphasis on research and development investments for longer term growth. Finally, we expect to continue to evaluate opportunities to acquire new product lines, technologies and companies.

Results of Operations

Comparison of years ended December 31, 2020 and 2019

Our fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. Fiscal year 2020 was 53 weeks and fiscal year 2019 was 52 weeks.

Total Revenues

The following table compares total revenues for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2020	2019	$	%
Rapid Immunoassay	$ 1,144,831	$ 191,736	$ 953,095	497 %
Cardiometabolic Immunoassay	242,933	266,505	(23,572)	(9)%
Molecular Diagnostic Solutions	222,964	21,716	201,248	927 %
Specialized Diagnostic Solutions	50,940	54,933	(3,993)	(7)%
Total revenues	$ 1,661,668	$ 534,890	$ 1,126,778	211 %

For the year ended December 31, 2020, total revenues increased 211% to $1,661.7 million. The Rapid Immunoassay category was the largest contributor to revenue growth, driven by the Sofia SARS Antigen and Sofia 2 Flu + SARS Antigen Immunoassays. Molecular Diagnostic Solutions sales grew $201.2 million over the prior year, driven by the Lyra SARS-CoV-2 assays. The decrease in Cardiometabolic Immunoassay and Specialized Diagnostic Solutions sales was mainly due to lower demand during the COVID-19 pandemic. Currency exchange rate impact for the period was favorable by $0.7 million, which had a minimal impact on the growth rate. See further discussion in Item 7A of this Annual Report for additional information related to our calculation and use of constant currency and constant currency revenue growth.

Gross Profit

Gross profit increased to $1,348.9 million, or 81% of revenue for the year ended December 31, 2020, compared to $320.8 million, or 60% of revenue for the year ended December 31, 2019. The increased gross profit was driven by the demand for our SARS-CoV-2 products, which drove improved product mix. In addition, higher production volumes contributed to increased manufacturing overhead absorption, which offset increases in spend required to expedite the production ramp. Gross margin improved compared to the same period in the prior year due to the same factors.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	For the year ended December 31,					
	2020		2019			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	Increase (decrease) $	Increase (decrease) %
Research and development	$ 84,292	5 %	$ 52,553	10 %	$ 31,739	60 %
Sales and marketing	$ 133,957	8 %	$ 111,114	21 %	$ 22,843	21 %
General and administrative	$ 66,586	4 %	$ 52,755	10 %	$ 13,831	26 %
Acquisition and integration costs	$ 3,694	0 %	$ 11,667	2 %	$ (7,973)	(68)%

Research and Development Expense

Research and development expense for the year ended December 31, 2020 increased from $52.6 million to $84.3 million due primarily to increased spending on Savanna, Sofia and next-generation instrument development projects. We also incurred higher labor, material and clinical trials spend associated with COVID-19 product development.

Research and development expenses include direct external costs such as fees paid to consultants, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, clinical trials and studies, facility costs and depreciation.

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization. We expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the year ended December 31, 2020 increased from $111.1 million to $134.0 million primarily due to higher employee-related costs, freight and bad debt expense, partially offset by reduced travel, meeting and trade show costs due to the COVID-19 travel restrictions.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2020 increased from $52.8 million to $66.6 million due to higher compensation costs from increased headcount to support the growth experienced in 2020 as well as improved performance in the period.

Acquisition and Integration Costs

Acquisition and integration costs of $3.7 million for the year ended December 31, 2020 primarily related to the evaluation of new business development opportunities. Acquisition and integration costs of $11.7 million for the year ended December 31, 2019 consisted primarily of global operation integration costs.

Other Expense, Net

The following table compares Other expense, net, for the years ended December 31, 2020 and 2019 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2020	2019	$	%
Interest and other expense, net	$ 9,623	$ 14,790	$ (5,167)	(35)%
Loss on extinguishment of debt	10,384	748	9,636	1,288 %
Total other expense, net	$ 20,007	$ 15,538	$ 4,469	29 %

Interest and other expense, net decreased from $14.8 million to $9.6 million. Interest and other expense, net primarily relates to accretion of interest on the deferred consideration, coupon and accretion of interest related to our Convertible Senior Notes and interest and amortization of deferred financing costs associated with any debt outstanding under our Credit Agreement. The decrease in interest and other expense, net over the prior year was primarily due to lower debt balances under the Company's Revolving Credit Facility and Convertible Senior Notes and lower deferred consideration liability outstanding. Such decrease was partially offset by a $1.1 million change in fair value of derivative liabilities associated with our Convertible Senior Notes conversion recorded in the second quarter of 2020.

Loss on extinguishment of debt of $10.4 million for the twelve months ended December 31, 2020 relates to the extinguishment of $5.9 million in aggregate principal of the Convertible Senior Notes converted and settled in cash during the period. Loss on extinguishment of debt of $0.7 million for the year ended December 31, 2019 relates to the extinguishment of $45.4 million in aggregate principal of the Convertible Senior Notes in exchange for the Company's common stock during the period.

Income Taxes

We recognized an income tax provision of $230.0 million, resulting in an effective tax rate of 22.1% for the year ended December 31, 2020. The primary drivers of the increased income tax expense in the year ended December 31, 2020 are the increased pre-tax profits offset by the lower proportional impact from excess tax benefits from stock-based compensation. In the year ended December 31, 2019, the excess tax benefits from stock-based compensation offset a greater portion of the tax expense from earnings.

Liquidity and Capital Resources

As of December 31, 2020 and 2019, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2020	2019
Cash, cash equivalents, and restricted cash	$ 489,941	$ 52,775
Amount available to borrow under the Revolving Credit Facility	$ 175,000	$ 175,000
Working capital including cash, cash equivalents, and restricted cash	$ 805,441	$ 96,336

As of December 31, 2020, we had $489.9 million in cash and cash equivalents, a $437.2 million increase from the prior year. Our cash requirements fluctuate as a result of numerous factors, such as cash generated from operations, progress in research and development or capital expansion projects and integration activities. We also intend to continue to evaluate candidates for new product lines, company or technology acquisitions or technology licensing and other strategic acquisitions and investments. If we decide to proceed with any such transactions, we may need to incur additional debt or issue additional equity to successfully complete the transactions.

Our primary source of liquidity, other than our holdings of cash and cash equivalents, has been cash flows from operations and financing. Cash generated from operations provides us with the financial flexibility we need to meet normal operating, investing and financing needs. We do not currently expect the impacts of the COVID-19 pandemic to adversely affect our liquidity and capital resources or our ability to meet financial commitments. We anticipate that our current cash and cash equivalents, together with cash provided by operating activities will be sufficient to fund our near-term capital and operating needs for at least the next 12 months.

Normal operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our primary short-term needs for capital, which are subject to change, include expenditures related to:

- acquisitions of equipment and other fixed assets in support of our manufacturing facility expansion;
- the continued advancement of research and development efforts;
- support of commercialization efforts related to our current and future products, including support of our direct sales force and field support resources;
- interest on and repayments of our deferred consideration, contingent consideration and lease obligations; and
- potential strategic acquisitions and investments.

Our Convertible Senior Notes matured on December 15, 2020. The Amended and Restated Credit Agreement provides us with a Revolving Credit Facility of $175.0 million and there was no balance outstanding as of December 31, 2020. The Revolving Credit Facility matures on August 31, 2023.

As of December 31, 2020, we have $11.9 million in fair value of contingent consideration and $116.0 million of deferred consideration associated with acquisitions to be settled in future periods.

On December 12, 2018, our Board of Directors authorized a stock repurchase program to purchase up to $50.0 million of the Company’s shares of common stock. On August 28, 2020, we announced an amendment to the stock repurchase program to purchase an additional $150.0 million of our shares of common stock through August 28, 2022. For the twelve months ended December 31, 2020, 257,329 shares of outstanding common stock were repurchased under our stock repurchase program for approximately $43.7 million and as of December 31, 2020, we had approximately $156.3 million available under the repurchase program.

Our future capital requirements and the adequacy of our available funds to service any long-term debt outstanding and to fund working capital expenditures and business development efforts will depend on many factors, including:

- our ability to realize revenue growth from our new technologies and create innovative products in our markets;
- outstanding debt and covenant restrictions;
- our ability to leverage our operating expenses to realize operating profits as we grow revenue;
- competing technological and market developments; and
- our entry into strategic collaborations with other companies or acquisitions of other companies or technologies to enhance or complement our product and service offerings

Cash Flow Summary

	Year ended December 31,	
(in thousands)	2020	2019
Net cash provided by operating activities	$ 629,763	$ 134,485
Net cash used for investing activities	(63,322)	(27,229)
Net cash used for financing activities	(130,277)	(98,282)
Effect of exchange rate changes on cash	1,002	106
Net increase in cash and cash equivalents	$ 437,166	$ 9,080

Cash provided by operating activities of $629.8 million during the twelve months ended December 31, 2020 reflects net income of $810.3 million and adjustments of $70.5 million primarily associated with depreciation, amortization, stock-based compensation, deferred taxes, loss on extinguishment of debt and accretion of interest on deferred consideration. Partially offsetting these inflows was a net working capital use of cash of $265.3 million primarily driven by increases in accounts receivable and product inventory, both associated with the increased demand due to the COVID-19 pandemic, partially offset by an increase in income taxes payable and accounts payable.

Cash provided by operating activities of $134.5 million during the year ended December 31, 2019 reflects net income of $72.9 million and non-cash adjustments of $76.8 million, primarily associated with depreciation, amortization, stock-based compensation and accretion of interest on deferred consideration. In addition, we used cash to fund our working capital requirements of $21.2 million, primarily driven by an increase in accounts receivable.

Our investing activities used $63.3 million during the twelve months ended December 31, 2020 primarily related to investments in manufacturing equipment, Sofia, Solana and Triage instruments available for lease, building improvements and scientific equipment. Our investing activities used $27.2 million during the year ended December 31, 2019 primarily related to payments for computer software, building improvements, Sofia, Solana and Triage instruments available for lease and manufacturing equipment.

We are currently planning approximately $300 million in capital expenditures over the next 12 months, of which approximately $33 million is expected to be funded through a contract with the National Institute of Health ("NIH"), entered into during the third quarter of 2020. See Note 1 in the Consolidated Financial Statements included in this Annual Report for further discussion of the NIH contract. We plan to fund the remainder of the capital expenditures with the cash on our balance sheet. The primary purpose for our capital expenditures is to invest in manufacturing capacity expansion, including implementation of our new manufacturing facility in Carlsbad, California, to acquire Sofia, Solana and Triage instruments, to acquire scientific equipment, to purchase or develop information technology and to implement facility improvements. We have $32.1 million in firm purchase commitments with respect to planned inventory purchases as of December 31, 2020.

Cash used by financing activities was $130.3 million during the twelve months ended December 31, 2020 primarily related to repurchases of common stock of $47.9 million, payment on Convertible Senior Notes and derivative liability of $43.4 million, payments on deferred consideration of $42.0 million, and acquisition contingent consideration of $6.0 million, partially offset by proceeds from issuance of stock of $9.6 million. Cash used by financing activities was $98.3 million during the year ended December 31, 2019 primarily related to payments on deferred consideration of $44.0 million, payments on the Revolving Credit Facility of $53.2 million, acquisition contingent consideration of $4.0 million and repurchases of common stock of $10.7 million, partially offset by proceeds from issuance of stock of $14.8 million from stock option exercises.

Off-Balance Sheet Arrangements

At December 31, 2020 and 2019, we did not have any relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Contractual Obligations

As of December 31, 2020, our future contractual obligations were as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Deferred consideration (1)	$ 124,000	$ 42,000	$ 82,000	$ —	$ —
Finance lease obligation (2)	18,287	1,215	2,535	2,117	12,420
Operating lease obligations (3)	137,166	12,043	22,677	22,553	79,893
Non-cancelable purchase commitment (4)	32,086	30,687	373	330	696
Total contractual obligations	$ 311,539	$ 85,945	$ 107,585	$ 25,000	$ 93,009

(1) Reflects the deferred consideration payments related to the acquisition of the BNP Business.

(2) Reflects our finance lease obligation primarily on the approximately 78,000 square-foot McKellar San Diego facility. The lease expires in December 2030 with options to extend for two additional 5-year periods. Finance lease obligations include payments through December 2025.

(3) Reflects future minimum lease obligations on facilities and equipment under operating leases in place as of December 31, 2020. The lease for the Summers Ridge facility is subject to certain must-take provisions related to one additional building that is not included in the operating lease obligations. The lease for the Rutherford facility with minimum lease payments of approximately $70.5 million is not included in the operating lease obligations as the lease was executed in 2021.

(4) Reflects our $32.1 million of non-cancelable commitments for planned inventory purchases under contractual arrangements.

We have entered into various licensing agreements, which largely require payments based on product sales as well as the achievement of specific milestones. Royalty and license expenses under these various royalty and licensing agreements collectively totaled $2.4 million, $1.1 million and $0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

We exclude liabilities pertaining to uncertain tax positions from our table of contractual obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities, nor the amount of the final cash settlement. As of December 31, 2020, we had approximately $16.6 million of liabilities associated with uncertain tax positions. See Note 4 in the Consolidated Financial Statements included in this Annual Report for further discussion of uncertain tax positions. The table also excludes $11.9 million in potential contingent consideration payments primarily related to the acquisition of the BNP Business and achievement of certain revenue targets under other acquisition agreements. We have not included amounts in the table because we cannot make a reasonably reliable estimate regarding the probability of the annual payments for the BNP Business. See Note 10 in the Consolidated Financial Statements included in this Annual Report for further discussion of our contingent consideration.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to reserve for contractual rebates, goodwill and intangible assets and income taxes. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Reserve for Contractual Rebates

The Company records revenues primarily from product sales. These revenues are recorded net of rebates that are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements and promotions. Rebates are calculated based upon historical experience and estimated distributor inventory balances and recorded as a reduction of sales with offsets to trade accounts receivable. As of December 31, 2020, the reserve related to contract rebates was $100.8 million.

Goodwill and Intangible Assets

The useful lives of intangible assets with definite lives are based on the expected number of years the asset will generate revenue or otherwise be used by us and the related amortization is based on the straight-line method. Goodwill, which has an indefinite life, is not amortized but instead is tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- any volatility or significant decline in our stock price and market capitalization compared to our net book value;
- loss of legal ownership or title to an asset;
- significant changes in our strategic business objectives and utilization of our assets; and
- the impact of significant negative industry or economic trends.

If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

For goodwill, the entity has the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. The quantitative impairment test compares the fair value of a reporting unit with the carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is recorded. We completed our annual evaluation for impairment of goodwill as of December 31, 2020 and determined that no impairment existed.

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. A valuation allowance may be established to reduce our deferred tax assets to the amount that is considered more likely than not to be realized through the generation of future taxable income and other tax planning opportunities. As of December 31, 2020, the Company has a valuation allowance of $2.3 million which represents the portion of the Company's deferred tax assets that management believes is not more likely than not to be realized. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist.

We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained during an audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe that we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcome of examinations by tax authorities in determining the adequacy of our provision for income taxes. See Note 4 in the Consolidated Financial Statements included in this Annual Report for more information on income taxes.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

For fixed rate debt, changes in interest rates will generally affect the fair value of the debt instrument, but not our earnings or cash flows. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to changes in interest rates.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, our cash equivalents as of December 31, 2020 consisted primarily of prime money market funds. The funds provide daily liquidity and may be subject to interest rate risk and fall in value if market interest rates increase. We do not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates.

Foreign Currency Exchange Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances of foreign subsidiaries, transaction gains and losses associated with intercompany loans with foreign subsidiaries and transactions denominated in currencies other than a location's functional currency.

For the year ended December 31, 2020, total revenues were $1,661.7 million, of which approximately $119.8 million in revenue was denominated in currencies other than the U.S. dollar. We believe constant currency and constant currency growth rate enhance the comparison of our financial performance from period-to-period, and to that of our competitors. Constant currency revenue excludes the impact from foreign currency fluctuations, which was favorable $0.7 million for the year ended December 31, 2020, and is calculated by translating current period revenues using prior period exchange rates, net of any hedging effect recognized in the current period. Constant currency revenue growth (expressed as a percentage) is calculated by determining the change in current period constant currency revenues over prior period revenues.

The major currencies to which our revenues are exposed are the Euro and the Chinese Yuan. A 100-basis point move in the average exchange rates (assuming a simultaneous and immediate 100 basis point change for the relevant period) would have resulted in an increase or decrease in our reported revenue for the year ended December 31, 2020 as follows (in thousands):

Currency		Year ended December 31, 2020
Chinese Renminbi	$	1,892
Euro	$	2,740

Our foreign currency management policy permits the use of derivative instruments, such as forward contracts, to reduce volatility in our results of operations resulting from foreign exchange rate fluctuations. We do not enter into foreign currency derivative instruments for trading purposes or to engage in speculative activity. See further discussion in Note 12 to the Notes to the Consolidated Financial Statements included in this Annual Report for additional information related to such forward contracts.

Item 8. Financial Statements and Supplementary Data

Index of Consolidated Financial Statements and Schedule

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Quidel Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Quidel Corporation (the Company) as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and schedule listed in the Index at Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with US generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 18, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Reserve for contractual rebates

Description of the Matter	As described in Note 1 to the consolidated financial statements, the Company records revenues from product sales net of contractual rebates that are estimated at the time of sale. As of December 31, 2020, the Company recognized an allowance on accounts receivable of $100.8 million in rebates. Auditing the Company's allowance for contractual rebates is especially challenging because the calculation involves estimating adjustments to revenue based upon a high volume of data including inputs from third-party sources, such as distributor inventory levels and historical distributor sales to end users. In addition, the determination of such adjustments includes estimating rebate percentages which are dependent on estimated end-user sales mix and customer contractual terms, which vary across customers.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of key controls over the Company's process to calculate the reserves for contractual rebates, including their evaluation of third-party data inputs utilized in the reserve and accrual calculations, as well as the accuracy of the Company's data inputs such as contractual pricing and estimated end user sales. Our audit procedures also included the evaluation of significant inputs through the evaluation of the Company's retrospective analysis of rebates claimed compared to actual payments issued, evaluation of estimates based on historical experience, and performance of analytical procedures and sensitivity analyses over the Company's significant inputs. We also tested the underlying data used in management's calculations for accuracy and completeness, which included inspection of source data supporting the inventory levels and rebate claims paid subsequent to period end.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

San Diego, California

February 18, 2021

QUIDEL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 489,941	$ 52,775
Accounts receivable, net	497,688	94,496
Inventories	113,798	58,086
Prepaid expenses and other current assets	40,975	16,870
Total current assets	1,142,402	222,227
Property, plant and equipment, net	110,481	79,762
Right-of-use assets	100,544	92,119
Goodwill	337,032	337,018
Intangible assets, net	122,431	148,112
Deferred tax asset	44,762	24,502
Other non-current assets	13,512	7,127
Total assets	$ 1,871,164	$ 910,867
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 86,316	$ 26,701
Accrued payroll and related expenses	34,781	17,286
Income tax payable	127,788	—
Operating lease liabilities	7,799	6,412
Contingent consideration	5,987	5,969
Deferred consideration	42,000	42,000
Convertible Senior Notes	—	12,661
Other current liabilities	32,290	14,862
Total current liabilities	336,961	125,891
Operating lease liabilities - non-current	100,706	93,227
Deferred consideration - non-current	73,951	109,382
Contingent consideration - non-current	5,909	10,566
Other non-current liabilities	20,934	11,981
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized; none issued or outstanding at December 31, 2020 and 2019	—	—
Common stock, $.001 par value per share; 97,500 shares authorized; 42,290 and 41,868 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	42	42
Additional paid-in capital	388,121	425,557
Accumulated other comprehensive loss	(431)	(463)
Retained earnings	944,971	134,684
Total stockholders' equity	1,332,703	559,820
Total liabilities and stockholders' equity	$ 1,871,164	$ 910,867

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share data)

	Year ended December 31,		
	2020	2019	2018
Total revenues	$ 1,661,668	$ 534,890	$ 522,285
Cost of sales	312,813	214,085	206,572
Gross profit	1,348,855	320,805	315,713
Research and development	84,292	52,553	51,649
Sales and marketing	133,957	111,114	108,987
General and administrative	66,586	52,755	44,951
Acquisition and integration costs	3,694	11,667	14,197
Total operating expenses	288,529	228,089	219,784
Operating income	1,060,326	92,716	95,929
Other expense, net			
Interest and other expense, net	(9,623)	(14,790)	(24,283)
Loss on extinguishment of debt	(10,384)	(748)	(8,262)
Total other expense, net	(20,007)	(15,538)	(32,545)
Income before income taxes	1,040,319	77,178	63,384
Provision (benefit) for income taxes	230,032	4,257	(10,799)
Net income	$ 810,287	$ 72,921	$ 74,183
Basic earnings per share	$ 19.24	$ 1.78	$ 1.95
Diluted earnings per share	$ 18.60	$ 1.73	$ 1.86
Shares used in basic per share calculation	42,124	40,860	37,995
Shares used in diluted per share calculation	43,591	43,111	42,554

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year ended December 31,		
	2020	2019	2018
Net income	$ 810,287	$ 72,921	$ 74,183
Other comprehensive income (loss)			
Changes in cumulative translation adjustment, net of tax	2,554	(322)	(139)
Changes in unrealized (losses) gains from cash flow hedges:			
Net unrealized (losses) gains on derivative instruments	(2,993)	716	—
Reclassification of net realized losses (gains) on derivative instruments included in net income	471	(718)	—
Total change in unrealized (losses) gains from cash flow hedges, net of tax	(2,522)	(2)	—
Comprehensive income	$ 810,319	$ 72,597	$ 74,044

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings (accumulated deficit)	Total stockholders' equity
Balance at December 31, 2017	34,540	$ 35	$ 239,489	$ —	$ (12,420)	$ 227,104
Issuance of common stock under equity compensation plans	1,237	—	17,047	—	—	17,047
Stock-based compensation expense	—	—	10,078	—	—	10,078
Issuance of shares in exchange for Convertible Senior Notes	3,699	4	200,215	—	—	200,219
Tax impact from the conversion of Convertible Senior Notes	—	—	2,162	—	—	2,162
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(100,726)	—	—	(100,726)
Repurchases of common stock	(90)	—	(4,344)	—	—	(4,344)
Changes in cumulative translation adjustment, net of tax	—	—	—	(139)	—	(139)
Net income	—	—	—	—	74,183	74,183
Balance at December 31, 2018	39,386	39	363,921	(139)	61,763	425,584
Issuance of common stock under equity compensation plans	1,152	2	16,797	—	—	16,799
Stock-based compensation expense	—	—	12,088	—	—	12,088
Issuance of shares in exchange for Convertible Senior Notes	1,497	1	86,427	—	—	86,428
Tax impact from the conversion of Convertible Senior Notes	—	—	568	—	—	568
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(43,516)	—	—	(43,516)
Repurchases of common stock	(167)	—	(10,728)	—	—	(10,728)
Other comprehensive loss, net of tax	—	—	—	(324)	—	(324)
Net income	—	—	—	—	72,921	72,921
Balance at December 31, 2019	41,868	42	425,557	(463)	134,684	559,820
Issuance of common stock under equity compensation plans	490	—	10,380	—	—	10,380
Stock-based compensation expense	—	—	18,969	—	—	18,969
Issuance of shares in exchange for Convertible Senior Notes	226	—	7,230	—	—	7,230
Tax impact from the conversion of Convertible Senior Notes	—	—	54	—	—	54
Derivative liabilities - Convertible Senior Notes elected to settle in cash	—	—	(26,180)	—	—	(26,180)
Repurchases of common stock	(294)	—	(47,889)	—	—	(47,889)
Other comprehensive income, net of tax	—	—	—	32	—	32
Net income	—	—	—	—	810,287	810,287
Balance at December 31, 2020	42,290	$ 42	$ 388,121	$ (431)	$ 944,971	$ 1,332,703

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2020	**2019**	**2018**
OPERATING ACTIVITIES			
Net income	$ 810,287	$ 72,921	$ 74,183
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation, amortization and other	49,089	47,827	46,266
Stock-based compensation expense	21,019	13,252	11,709
Impairment loss	—	1,481	—
Amortization of debt discount and deferred issuance costs	771	1,582	3,952
Change in fair value of acquisition contingencies	1,405	1,467	1,114
Accretion of interest on deferred consideration	6,569	8,224	10,000
Amortization of inventory step-up to fair value	—	—	3,650
Net change in operating lease right-of-use assets and liabilities	434	3,964	—
Change in deferred tax assets and liabilities	(20,211)	(1,742)	(20,458)
Change in fair value of derivative liabilities - Convertible Senior Notes	1,084	—	—
Loss on extinguishment of debt	10,384	748	8,262
Changes in assets and liabilities:			
Accounts receivable	(402,094)	(36,059)	8,236
Inventories	(54,903)	9,143	(3,974)
Prepaid expenses and other current and non-current assets	(14,264)	4,314	(12,681)
Accounts payable	52,226	2,434	(331)
Accrued payroll and related expenses	16,024	(1,037)	1,674
Income taxes payable	137,708	4,175	2,082
Other current and non-current liabilities	14,235	1,791	2,661
Net cash provided by operating activities	629,763	134,485	136,345
INVESTING ACTIVITIES			
Acquisitions of property, equipment and intangibles	(64,927)	(27,229)	(31,689)
Proceeds from government assistance allocated to fixed assets	1,605	—	—
Proceeds from sale of Summers Ridge Property	—	—	146,644
Net cash (used for) provided by investing activities	(63,322)	(27,229)	114,955
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	9,613	14,782	17,047
Payments of debt issuance costs	—	—	(513)
Payments on finance lease obligation	(511)	(371)	(130)
Payments on Revolving Credit Facility	—	(53,188)	(40,000)
Repurchases of common stock	(47,889)	(10,728)	(4,344)
Payments on acquisition contingent consideration	(6,044)	(4,044)	(6,303)
Payments of deferred consideration	(42,000)	(44,000)	(46,000)
Payment on Convertible Senior Note and Derivative Liability	(43,446)	—	—
Payments of Term Loan	—	—	(161,813)
Transaction costs related to debt exchange	—	(733)	(2,002)
Net cash used for financing activities	(130,277)	(98,282)	(244,058)
Effect of exchange rate changes on cash	1,002	106	367
Net increase in cash and cash equivalents	437,166	9,080	7,609
Cash and cash equivalents, beginning of period	52,775	43,695	36,086
Cash and cash equivalents, at end of period	$ 489,941	$ 52,775	$ 43,695

	Year ended December 31,		
	2020	2019	2018
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$ 480	$ 2,295	$ 7,929
Cash paid during the period for income taxes	$ 109,912	$ 2,189	$ 6,923
Purchase of property, equipment and intangibles by incurring current liabilities	$ 7,160	$ 1,040	$ 1,785
Accrued receivable for capital expenditures to be reimbursed under a government contract	$ 15,854	$ —	$ —
Reduction of other current liabilities upon issuance of restricted share units	$ 767	$ 2,018	$ —
Extinguishment of Convertible Senior Notes through issuance of stock	$ 7,230	$ 86,428	$ 200,219
Principal amount of Term Loan exchanged for Revolving Credit Facility	$ —	$ —	$ 83,187

See accompanying notes.

Note 1. Company Operations and Summary of Significant Accounting Policies

Quidel Corporation (the "Company") commenced operations in 1979. The Company operates in one business segment, which develops, manufactures and markets diagnostic testing solutions. These diagnostic tests can be categorized in the following product categories: Rapid Immunoassay, Cardiometabolic Immunoassay, Specialized Diagnostic Solutions and Molecular Diagnostic Solutions. The Company sells its products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics and wellness screening centers. The Company markets its products through a network of distributors and a direct sales force.

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with generally accepted accounting principles in the U.S.

Consolidation—The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Cash and Cash Equivalents—The Company considers cash equivalents to be highly liquid investments with a maturity at the date of purchase of three months or less. The Company invests its cash equivalents primarily in money market funds with high quality institutions.

Accounts Receivable—The Company sells its products directly to hospitals and reference laboratories as well as to distributors in the U.S. and internationally (see Note 9). The Company periodically assesses the financial strength of these customers and establishes reserves for anticipated losses when necessary, which historically have not been material. The balance of accounts receivable is net of reserves of $103.4 million and $16.0 million at December 31, 2020 and 2019, respectively, of which the reserve related to contract rebates was $100.8 million and $15.7 million, respectively.

Concentration of Credit Risk—Financial instruments that potentially subject the Company to significant concentrations of credit risk consists principally of trade accounts receivable and cash equivalents.

The Company performs credit evaluations of its customers' financial condition and limits the amount of credit extended when deemed necessary, but generally requires no collateral. Credit quality is monitored regularly by reviewing credit history. The Company believes that the concentration of credit risk in its trade accounts receivables is moderated by its credit evaluation process, relatively short collection terms, the high level of credit worthiness of its customers, and letters of credit issued on the Company's behalf. Potential credit losses are limited to the gross value of accounts receivable.

Inventories—Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. The Company reviews the components of its inventory periodically for excess, obsolete and impaired inventory and records a reduction to the carrying value when identified.

Property, Plant and Equipment—Property, plant and equipment is recorded at cost and depreciated over the estimated useful lives of the assets (three to fifteen years) using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the shorter of the lease term or the estimated useful lives of the related assets.

Goodwill and Intangible Assets—Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives, except for indefinite-lived intangibles such as goodwill. Software development costs associated with software to be leased or otherwise marketed are expensed as incurred until technological feasibility has been established. After technological feasibility is established, software development costs are capitalized and amortized on a straight-line basis over the estimated product life.

Convertible Debt—The Company accounts for convertible debt instruments that may be settled in cash upon conversion (including combination settlement of cash equal to the "principal portion" and delivery of the "share amount" in excess of the conversion value over the principal portion in shares of common stock and/or cash) by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. The Company determines the carrying amount of the liability component by measuring the fair value of similar debt instruments that do not have the conversion feature. If no similar debt instrument exists, the Company estimates fair value by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities.

Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense. See Note 3 for additional discussion of the Convertible Senior Notes issued in December 2014.

Revenue Recognition—The Company records revenues primarily from product sales. These revenues are recorded net of rebates and other discounts. These rebates and discounts are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Rebates and discounts are calculated based upon historical experience, estimated discounting levels and estimated distributor inventory balances and recorded as a reduction of sales with offsets to accounts receivable and other current liabilities, respectively.

Revenue is recognized when control of the products is transferred to the customers in an amount that reflects the consideration the Company expects to receive from the customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract and the contract price, allocating the contract price to the distinct performance obligations in the contract and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. A performance obligation is considered to be satisfied once the control of a product is transferred to the customer or the service is provided to the customer, meaning the customer has the ability to use and obtain the benefit of the goods or service.

A portion of product sales includes revenues for diagnostic kits, which are utilized on leased instrument systems under the Company's "reagent rental" program. The reagent rental program provides customers the right to use the instruments at no separate cost to the customer in consideration for a multi-year agreement to purchase annual minimum amounts of consumables ("reagents" or "diagnostic kits"). When an instrument is placed with a customer under a reagent rental agreement, the Company retains title to the equipment and it remains capitalized on the Company's Consolidated Balance Sheets as property, plant and equipment, net. The instrument is depreciated on a straight-line basis over the lesser of the lease term or life of the instrument. Depreciation expense is recorded in cost of sales included in the Consolidated Statements of Income. Instrument and consumables under the reagent rental agreements are deemed two distinct performance obligations. Though the instrument and consumables do not have any use to customers without one another, they are not highly interdependent because they do not significantly affect each other. The Company would be able to fulfill its promise to transfer the instrument even if its customers did not purchase any consumables and the Company would be able to fulfill its promise to provide the consumables even if customers acquired instruments separately. The contract price is allocated between these two performance obligations based on the relative standalone selling prices. The instrument is considered an operating lease and revenue allocated to the instrument will be separately disclosed, if material.

Government Assistance— During the year ended December 31, 2020, the Company entered into a contract with the National Institute of Health ("NIH"), through its newly launched Rapid Acceleration of Diagnostics - Advanced Technology Platforms initiative, to support the Company's expansion of its manufacturing capacity for its diagnostic assays that test for the SARS-CoV-2 antigen. The contract provides for consideration to the Company of up to $65.0 million and has a performance period of one year, which began in July 2020. The contract includes key deliverables and milestones that will directly support the upgrade and addition of new manufacturing lines as well as the outfitting of a new distribution center. The Company will also provide instruments and assays to NIH. There are no refund provisions under the contract.

Consideration from the contract is allocated to each deliverable identified within the contract using a relative fair value allocation method and recognized when there is reasonable assurance the Company will meet the milestones and receive the consideration. Consideration allocated to the delivery of instruments and assays are recognized in accordance with the Company's existing revenue recognition policy described above. Consideration that relates to capital expenditures is recorded as a reduction to the carrying value of such assets and amortized over the useful life of the assets. Consideration allocated to the remainder of the contract is recorded as reductions to the related expense. During the year ended December 31, 2020, the Company incurred $15.9 million in capital expenditures, which will be reimbursed under this contract as future milestones are met. Therefore, the Company accrued such unbilled receivables in prepaid expenses and other current assets as of December 31, 2020.

Research and Development Costs—Research and development costs are charged to operations as incurred. In conjunction with certain third-party service agreements, the Company is required to make periodic payments based on achievement of certain milestones. The costs related to these research and development services are also charged to operations as incurred.

Product Shipment Costs—Product shipment costs are included in sales and marketing expense in the accompanying Consolidated Statements of Income. Shipping and handling costs were $14.2 million, $9.5 million and $8.3 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $1.1 million, $1.3 million and $0.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Income Taxes—Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company's policy is to recognize the interest expense and penalties related to income tax matters as a component of the income tax provision.

Fair Value of Financial Instruments— The Company uses the fair value hierarchy established in Accounting Standards Codification ("ASC") Topic 820*, Fair Value Measurements and Disclosures,* which requires that the valuation of assets and liabilities subject to fair value measurements be classified and disclosed by the Company in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, accounts receivables, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

Stock-Based Compensation—Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option. For stock options with graded vesting, the Company ensures that the cumulative amount of compensation expense recognized at the end of any reporting period at least equals the portion of the stock option that has vested at that date. The total number of stock options expected to vest is adjusted by estimated forfeiture rates. The Company determined the estimated fair value of each stock option on the date of grant using the Black-Scholes option valuation model. The fair value of restricted stock units is determined based on the closing market price of the Company's common stock on the grant date. Compensation expense for time-based restricted stock units ("RSUs") is measured at the grant date and recognized ratably over the vesting period. A portion of the restricted stock granted are performance-based and vesting is tied to achievement of specific Company goals over a three-year time period, subject to early vesting upon achievement of the performance goals. For purposes of measuring compensation expense for performance-based restricted stock units ("PSUs"), the number of shares ultimately expected to vest is estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The grant date of the PSUs takes place when the grant is authorized and the specific achievement goals are communicated.

Comprehensive Income—Comprehensive income includes unrealized gains and losses which are related to the cumulative translation adjustments and derivative instruments excluded from the Company's Consolidated Statements of Income.

Use of Estimates—The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Accounting Periods—Each of the Company's fiscal quarters end on the Sunday closest to the end of the calendar quarter. The Company's fiscal year ended January 3, 2021 was 53 weeks and the Company's fiscal years ended December 29, 2019 and December 30, 2018 were 52 weeks. For ease of reference, the calendar year end dates are used herein.

Leases—Lease liabilities represent the obligation to make lease payments and right-of-use ("ROU") assets represent the right to use the underlying asset during the lease term. Lease liabilities and ROU assets are recognized at the commencement date of the lease based on the present value of lease payments over the lease term at the commencement date. When the implicit rate is unknown, an incremental borrowing rate based on the information available at the commencement date is used in

determining the present value of the lease payments. Options to extend or terminate the lease are included in the determination of the lease term when it is reasonably certain that the Company will exercise such options.

For certain classes of assets, the Company accounts for lease and non-lease components as a single lease component. Variable lease payments, including those related to changes in the consumer price index, are recognized in the period in which the obligation for those payments are incurred and are not included in the measurement of the ROU assets or lease liabilities. Short-term leases are excluded from the calculation of the ROU assets and lease liabilities.

Operating leases are included in right-of-use assets, operating lease liabilities and operating lease liabilities non-current in the Consolidated Balance Sheet. Finance leases are included in property, plant and equipment, net, other current liabilities and other non-current liabilities.

Note 2. Balance Sheet Account Details

Prepaid expenses and other current assets

The following is a summary of prepaid expenses and other current assets (in thousands):

	December 31,	
	2020	2019
Unbilled receivables	$ 16,041	$ —
Other receivables	15,442	7,857
Prepaid expenses	7,335	4,568
Other	2,157	4,445
Total prepaid expenses and other current assets	$ 40,975	$ 16,870

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. The following is a summary of inventories (in thousands):

	December 31,	
	2020	2019
Raw materials	$ 58,264	$ 23,294
Work-in-process (materials, labor and overhead)	31,359	20,514
Finished goods (materials, labor and overhead)	24,175	14,278
Total inventories	$ 113,798	$ 58,086

Property, Plant and Equipment, net

The following is a summary of property, plant and equipment (in thousands):

	December 31,	
	2020	2019
Equipment, furniture and fixtures	$ 91,838	$ 80,599
Building and improvements	49,014	46,878
Leased instruments	60,722	47,656
Land	1,080	1,080
Construction in Progress	32,595	15,748
Total property, plant and equipment, gross	235,249	191,961
Less: accumulated depreciation and amortization	(124,768)	(112,199)
Total property, plant and equipment, net	$ 110,481	$ 79,762

Construction in progress includes instruments that have not been placed at a customer under a lease agreement that will be reclassified to leased instruments once placed at a customer site. The total expense for depreciation of fixed assets and

amortization of leasehold improvements was $20.8 million, $19.4 million and $17.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. Maintenance and minor repairs are charged to operations as incurred.

Goodwill and Intangible Assets

The Company had goodwill of $337.0 million as of December 31, 2020, which remains consistent with December 31, 2019. Finite-lived intangible assets consisted of the following (dollar amounts in thousands):

		December 31, 2020			December 31, 2019		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	9.1	$ 112,100	$ (71,426)	$ 40,674	$ 112,100	$ (64,632)	$ 47,468
Customer relationships	7.0	122,584	(60,688)	61,896	122,178	(44,045)	78,133
License agreements	9.9	6,518	(5,312)	1,206	6,509	(4,931)	1,578
Patent and trademark costs	10.8	28,740	(13,038)	15,702	28,740	(10,331)	18,409
Software development costs	5.0	8,743	(5,790)	2,953	7,432	(4,908)	2,524
Total finite-lived intangible assets		$ 278,685	$ (156,254)	$ 122,431	$ 276,959	$ (128,847)	$ 148,112

Amortization expense related to the capitalized software costs was $0.9 million, $0.8 million and $1.0 million for the years ended December 31, 2020, 2019 and 2018, respectively. Amortization expense (including capitalized software costs) was $27.3 million, $27.5 million and $28.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

The expected future annual amortization expense of the Company's finite-lived intangible assets held as of December 31, 2020 is as follows (in thousands):

For the years ending December 31,	Amortization expense
2021	$ 27,452
2022	26,922
2023	26,211
2024	21,634
2025	7,979
Thereafter	12,233
Total	$ 122,431

Other current liabilities

The following is a summary of other current liabilities (in thousands):

	December 31,	
	2020	2019
Customer incentives	$ 11,934	$ 7,369
Deferred revenue	3,733	336
Derivative liabilities	3,061	433
Other	13,562	6,724
Total other current liabilities	$ 32,290	$ 14,862

Note 3. Debt

Convertible Senior Notes

In December 2014, the Company issued $172.5 million aggregate principal amount of 3.25% Convertible Senior Notes due 2020. The Company accounted separately for the liability and equity components of the Convertible Senior Notes in

accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. The guidance required the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company had no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the Convertible Senior Notes without the conversion option. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry with similar credit ratings and with similar maturity, the Company estimated the implied interest rate of its Convertible Senior Notes to be 6.9%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, which were defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Convertible Senior Notes, which resulted in a fair value of the liability component of $141.9 million upon issuance, calculated as the present value of implied future payments based on the $172.5 million aggregate principal amount. The $30.7 million difference between the cash proceeds of $172.5 million and the estimated fair value of the liability component was recorded in additional paid-in capital, net of tax and issuance costs, as the Convertible Senior Notes were not considered redeemable. During 2020 the remaining aggregate principal amount of Convertible Senior Notes were settled or matured on December 15, 2020 and at December 31, 2020 no amounts were outstanding.

The following table summarizes the amount of interest expense for the following periods (in thousands):

	Year ended December 31,		
	2020	2019	2018
Amortization of debt discount and deferred issuance costs	$ 368	$ 1,179	$ 3,094
Coupon interest	195	1,103	2,992
Total Interest Expense	$ 563	$ 2,282	$ 6,086

The following table summarizes information about the settlement of the Convertible Senior Notes during the year ended December 31, 2020 (dollars in thousands):

	Year ended December 31, 2020
Principal amount settled	$ 13,131
Number of shares of common stock issued	225,955
Payment on Convertible Senior Note and Derivative Liability	$ 43,446

Revolving Credit Facility

On August 31, 2018, the Company entered into an Amended and Restated Credit Agreement (the "Credit Agreement") which provides the Company with a $175.0 million Revolving Credit Facility. The Company repaid the remaining principal during the year ended December 31, 2019 and no balance remained outstanding as of December 31, 2020. The Credit Agreement has a term of five years and matures on August 31, 2023.

Loans will bear interest at a rate equal to (i) the London Interbank Offered Rate ("LIBOR") plus the "applicable rate" or (ii) the "base rate" (defined as the highest of (a) the Bank of America prime rate, (b) the Federal Funds rate plus one-half of one percent and (c) LIBOR plus one percent) plus the "applicable rate." The applicable rate is determined in accordance with a pricing grid based on the Company's Consolidated Leverage Ratio (as defined in the Credit Agreement) ranging from 1.75% to 2.50% per annum for LIBOR rate loans and from 0.75% to 1.50% per annum for base rate loans. In addition, the Company pays a commitment fee on the unused portion of the Credit Agreement based on the Company's Consolidated Leverage Ratio ranging from 0.15% to 0.30% per annum.

The Revolving Credit Facility is guaranteed by certain material domestic subsidiaries of the Company (the "Guarantors") and is secured by liens on substantially all of the assets of the Company and the Guarantors, excluding real property and certain other types of excluded assets, and contains affirmative and negative covenants that are customary for credit agreements of this nature. The negative covenants include, among other things, limitations on asset sales, mergers, indebtedness, liens, dividends and other distributions, investments and transactions with affiliates. The Credit Agreement contains two financial covenants: (i) maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) as of the last day of each fiscal quarter of 3.50 to 1.00, which ratio may be increased to 4.50 to 1.00 in case of certain qualifying acquisitions; and (ii) a minimum Consolidated Fixed Charge Coverage Ratio (as defined in the Credit Agreement) of 1.25 to 1.00 as of the end of any fiscal quarter for the most recently completed four fiscal quarters. The Company was in compliance with all financial covenants as of December 31, 2020.

Interest expense recognized on the Credit Agreement including amortization of deferred issuance cost was $0.7 million, $1.7 million, and $6.5 million, respectively, for the years ended December 31, 2020, 2019 and 2018.

Note 4. Income Taxes

Significant components of the provision (benefit) for income taxes are as follows (in thousands):

	December 31,		
	2020	2019	2018
Current:			
Federal	$ 198,498	$ 1,559	$ —
State	34,608	746	755
Foreign	1,136	2,007	6,575
Total current provision	234,242	4,312	7,330
Deferred:			
Federal	(2,855)	1,234	(9,970)
State	(1,104)	(1,186)	(7,944)
Foreign	(251)	(103)	(215)
Total deferred (benefit) provision	(4,210)	(55)	(18,129)
Provision (benefit) for income taxes	$ 230,032	$ 4,257	$ (10,799)

The Company's income before income taxes was subject to taxes in the following jurisdictions for the following periods (in thousands):

	December 31,		
	2020	2019	2018
United States	$ 1,035,752	$ 70,606	$ 46,592
Foreign	4,567	6,572	16,792
Income before income taxes	$ 1,040,319	$ 77,178	$ 63,384

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2020 and 2019 are shown below (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Lease liability	$ 24,790	$ 22,009
Intangible assets	2,747	3,951
Allowance for returns and discounts	27,277	5,266
Stock-based compensation	8,367	5,197
Tax credit carryforwards	11,770	13,846
Other, net	10,426	6,610
Total deferred tax assets	85,377	56,879
Valuation allowance for deferred tax assets	(2,281)	(2,353)
Total deferred tax assets, net of valuation allowance	83,096	54,526
Deferred tax liabilities:		
Right-of-use assets	(22,969)	(20,334)
Intangible assets	(1,133)	(1,633)
Property, plant and equipment	(14,232)	(8,057)
Total deferred tax liabilities	(38,334)	(30,024)
Net deferred tax assets	$ 44,762	$ 24,502

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. For the three years ended December 31, 2020, the Company has demonstrated positive cumulative pre-tax book income. Such objective positive evidence allowed the Company to consider other subjective evidence, such as the Company's projections for future profitability, to determine the realizability of its deferred tax assets. On the basis of this evaluation, during the year ended December 31, 2020, the Company decreased the valuation allowance by $0.1 million related to the U.S. Foreign Tax Credit.

The valuation allowance of $2.3 million as of December 31, 2020 represents the portion of the deferred tax asset that management could not conclude was more likely than not to be realized. The amount of the deferred tax assets considered realizable could be adjusted in the future based on changes in available positive and negative evidence.

As of December 31, 2020, the Company had no federal net operating loss ("NOL") carryforwards. The Company had state NOLs of approximately $5.9 million which will begin to expire in 2030 unless previously utilized. The Company has no federal research credits. The Company has federal foreign tax credits of $2.3 million which will begin to expire on December 31, 2028 unless previously utilized. The Company has state research credits of $12.3 million, of which none expire.

Pursuant to Internal Revenue Code Sections 382 and 383, the Company's use of its NOL and tax credit carryforwards may be limited as a result of cumulative changes in ownership of more than 50% over a three-year period. As of December 31, 2020, the Company does not believe any historical ownership change has limited the use of its NOLs or tax credit carryforwards.

The reconciliation of income tax computed at the federal statutory rate to the provision (benefit) for income taxes from continuing operations is as follows (in thousands):

	Year ended December 31,		
	2020	2019	2018
Tax expense at statutory tax rate	$ 218,467	$ 16,207	$ 13,311
State tax expense, net of federal tax	30,289	1,061	1,526
Permanent differences	3,843	611	635
Federal and state research credits—current year	(5,037)	(4,269)	(3,628)
Stock-based compensation	(13,867)	(10,408)	(9,286)
Change in valuation allowance	(72)	523	(13,374)
Foreign Derived Intangible Income Deduction (FDII)	(8,589)	(159)	(786)
Other	4,998	691	803
Provision (benefit) for income taxes	$ 230,032	$ 4,257	$ (10,799)

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	Year ended December 31,		
	2020	2019	2018
Beginning balance	$ 17,236	$ 15,245	$ 9,565
(Decreases) increases related to prior year tax positions	(2,351)	287	(558)
Increases related to current year tax positions	7,726	2,209	6,238
Expiration of the statute of limitations for the assessment of taxes	(54)	(505)	—
Ending balance	$ 22,557	$ 17,236	$ 15,245

As of December 31, 2020, 2019 and 2018, the Company had unrecognized tax benefits of $22.6 million, $17.2 million, and $15.2 million respectively, of which $15.0 million and $11.1 million and $9.3 million, respectively, would reduce the Company's annual effective tax rate, if recognized. It is reasonably possible that the amount of unrecognized tax benefits in various jurisdictions may decrease in the next 12 months due to settlements with tax authorities. However, due to the uncertainty surrounding the timing of these events, an estimate in the change within the next 12 months cannot be made at this time. The Company's policy is to recognize the interest expense and penalties related to income tax matters as a component of the income tax expense. The Company had accrued interest and penalties associated with uncertain tax positions of $0.5 million as of December 31, 2020, $0.4 million as of December 31, 2019 and $0.3 million as of December 31, 2018. Interest expense, net of accrued interest (reversed), was approximately $0.1 million for the years ended December 31, 2020, 2019 and 2018.

The Company is subject to periodic audits by domestic and foreign tax authorities.

As of December 31, 2020, the Company no longer has any federal net operating loss or credit carryforwards. However, because of utilization of tax attributes generated in tax years 2012 and later on its tax returns still open by statute, the Company's federal tax years from 2012 and forward are still subject to examination by tax authorities. Due to the carryforward of unutilized California net operating losses and credits, the Company's California tax returns for years 2001 and forward are subject to examination by tax authorities. The Company believes that it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020. The CARES Act provides for, among other things, refundable payroll tax credits, deferment of employer side social security payments and technical amendments regarding the income tax depreciation of qualified improvement property placed in service after December 31, 2017. The Company is benefiting only from the technical amendments regarding retroactive accelerated income tax depreciation on certain of our leasehold improvement assets.

Note 5. Stockholders' Equity

Preferred Stock. The Company's certificate of incorporation, as amended, authorizes the issuance of up to 5 million preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding as of December 31, 2020, 2019 or 2018.

Equity Incentive Plan. The Company grants stock options, RSUs and PSUs to employees and non-employee directors under its 2018 Equity Incentive Plan (the "2018 Plan"). The Company previously granted stock options under its 2016 Equity Incentive Plan (the "2016 Plan"), Amended and Restated 2010 Equity Incentive Plan (the "2010 Plan") and the Amended and Restated 2001 Equity Incentive Plan (the "2001 Plan"). The 2016 Plan, 2010 Plan and 2001 Plan were terminated at the time of adoption of the 2018 Plan, but the terminated Plans continue to govern outstanding options granted thereunder. The Company has stock options, RSUs and PSUs outstanding, which were issued under each of these equity incentive plans to certain employees and directors. Stock options granted under these plans have terms ranging up to ten years, have exercise prices ranging from $14.56 to $248.41 per share, and generally vest over four years. As of December 31, 2020, approximately 2.2 million shares remained available for grant and 3.8 million shares of common stock were reserved for future issuance under the 2018 Plan.

Restricted Stock Units. The Company grants both RSUs and PSUs to certain officers, directors and management. Until the restrictions lapse, ownership of the affected restricted stock units granted to the Company's officers, directors and management is conditional upon continuous employment with the Company.

For the years ended December 31, 2020, 2019 and 2018, the Company granted approximately 0.2 million, 0.3 million and 0.2 million shares, respectively, of RSUs to Board of Directors, officers and management, which either have a time-based four-year vesting provision or performance-based vesting provisions.

During the years ended December 31, 2020, 2019 and 2018, RSUs were granted to certain members of the Board of Directors in lieu of cash compensation as a part of the Company's non-employee director's deferred compensation program. The compensation expense associated with these RSU grants were $0.5 million, $0.5 million and $0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Employee Deferred Bonus Compensation Program. For the years ended December 31, 2020, 2019 and 2018, certain employees of the Company were eligible to participate in the Company's deferred bonus compensation program with respect to any payments received under the Company's cash incentive plan. Participating employees could elect to receive 50% or 100%

of the cash value of their cash bonus in the form of fully vested RSUs plus a premium as additional RSUs, issued under the 2018 Plan. The premium RSUs are subject to a one-year vesting requirement from the date of issuance. The additional premium will be determined based on the length of time of the deferral period selected by the participating employee as follows: (i) if one year from the date of grant, a premium of 10% on the amount deferred, (ii) if two years from the date of grant, a premium of 20% on the amount deferred, or (iii) if four years from the date of grant, a premium of 30% on the amount deferred.

Employee Stock Purchase Plan. Under the Company's Amended and Restated 1983 Employee Stock Purchase Plan (the "ESPP"), full-time employees are allowed to purchase common stock through payroll deductions (which cannot exceed 10% of the employee's compensation) at the lower of 85% of fair market value at the beginning or end of each six-month purchase period. As of December 31, 2020, 86,571 shares remained available for future issuance.

Share Repurchase Program. On December 12, 2018, the Board of Directors authorized a stock repurchase program pursuant to which up to $50.0 million of the Company's shares of common stock may be purchased through December 12, 2020. On August 28, 2020, the Board authorized an increase of additional $150.0 million to the Company's existing stock repurchase program and also extended the repurchase authorization through August 28, 2022. During the year ended December 31, 2020, 257,329 shares of outstanding common stock were repurchased under the revised share repurchase program. There were no repurchases during 2019. At December 31, 2020, $156.3 million remained available under the new repurchase program.

Note 6. Stock-Based Compensation

Stock-based compensation expense was as follows (in thousands):

	Year ended December 31,		
	2020	2019	2018
Cost of sales	$ 2,012	$ 1,162	$ 763
Research and development	3,372	2,332	2,266
Sales and marketing	6,009	3,497	2,843
General and administrative	9,626	6,261	5,837
Total stock-based compensation expense	$ 21,019	$ 13,252	$ 11,709

For the years ended December 31, 2020, 2019 and 2018, the Company recorded $2.2 million, $1.4 million and $1.6 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 5. During the years ended December 31, 2020, 2019 and 2018, $2.1 million, $0.8 million and $1.6 million, respectively, was initially recorded as a component of accrued payroll and related expenses associated with the deferred bonus compensation program.

Stock Options

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The estimated fair value of each stock option was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Year ended December 31,		
	2020	2019	2018
Risk-free interest rate	1.18 %	2.51 %	2.49 %
Expected option life (in years)	5.12	5.68	6.29
Volatility rate	41 %	39 %	36 %
Dividend rate	0 %	0 %	0 %

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility is based on the historical volatility of the Company's stock. The risk-free interest rate is based on the U.S. Treasury yield curve over the expected term of the option. The Company has never paid any cash dividends on its common stock, and does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model. The Company's estimated forfeiture rate is based on its historical experience and future expectations.

The Company's determination of fair value is affected by the Company's stock price as well as a number of assumptions that require judgment. The weighted-average fair value per share was $36.84, $23.67 and $18.76 for options granted during the years ended December 31, 2020, 2019 and 2018, respectively. The total intrinsic value was $51.8 million, $49.8 million and $38.2 million for options exercised during the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, total unrecognized compensation expense related to stock options was approximately $7.1 million and the related weighted-average period over which it is expected to be recognized is approximately 2.0 years. The maximum contractual term of the Company's stock options is ten years.

A summary of the status of stock option activity for the years ended December 31, 2018, 2019 and 2020 is as follows (in thousands, except price data and years):

	Number of Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2017	2,659	$ 18.54		
Granted	159	46.50		
Exercised	(891)	17.07		
Forfeited	(50)	21.19		
Outstanding at December 31, 2018	1,877	21.53		
Granted	169	59.18		
Exercised	(1,091)	19.22		
Forfeited	(11)	49.71		
Outstanding at December 31, 2019	944	30.63		
Granted	145	96.34		
Exercised	(317)	21.03		
Forfeited	(12)	43.34		
Outstanding at December 31, 2020	760	$ 46.95	6.79	$ 101,535
Vested and expected to vest at December 31, 2020	739	$ 46.03	6.74	$ 99,456
Exercisable at December 31, 2020	327	$ 23.32	5.16	$ 51,062

Restricted Stock Units

A summary of the status of restricted stock unit activity for the years ended December 31, 2018, 2019 and 2020 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
Non-vested at December 31, 2017	746	$ 20.88
Granted	242	49.97
Vested	(296)	21.70
Forfeited	(16)	28.40
Non-vested at December 31, 2018	676	30.75
Granted	279	59.75
Vested	(148)	24.26
Forfeited	(21)	43.90
Non-vested at December 31, 2019	786	41.88
Granted	235	101.20
Vested	(123)	26.58
Forfeited	(20)	58.32
Non-vested at December 31, 2020	878	$ 59.60

The total amount of unrecognized compensation expense related to non-vested restricted stock units as of December 31, 2020 was approximately $25.2 million, which is expected to be recognized over a weighted-average period of approximately 1.4 years.

Note 7. Earnings Per Share

Basic earnings per share ("EPS") is computed by dividing net income by the weighted-average number of common shares outstanding. Diluted EPS is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of shares issuable from stock options, unvested RSUs and the 3.25% Convertible Senior Notes. Potentially dilutive common shares from outstanding stock options and unvested RSUs are determined using the average share price for each period under the treasury stock method.

Potentially dilutive shares from the Convertible Senior Notes are determined using the if-converted method. Under the provisions of the if-converted method, the Convertible Senior Notes are assumed to be converted and the resulting common shares are included in the denominator of the EPS calculation and the interest expense, net of tax, recorded in connection with the Convertible Senior Notes is added back to net income. The Convertible Senior Notes have a dilutive impact when the average market price of the Company's common stock exceeds the applicable conversion price of the notes. The Convertible Senior Notes became convertible on March 31, 2018 and matured on December 15, 2020.

The following table reconciles net income and the weighted-average shares used in computing basic and diluted EPS in the respective periods (in thousands):

	Year ended December 31,		
	2020	2019	2018
Numerator:			
Net income used for basic earnings per share	$ 810,287	$ 72,921	$ 74,183
Interest expense on Convertible Senior Notes, net of tax	445	1,848	4,927
Net income used for diluted earnings per share, if-converted method	$ 810,732	$ 74,769	$ 79,110
Basic weighted-average common shares outstanding	42,124	40,860	37,995
Dilutive potential shares issuable from Convertible Senior Notes	295	1,062	2,850
Dilutive potential shares issuable from stock options and unvested RSUs	1,172	1,189	1,709
Diluted weighted-average common shares outstanding, if-converted	43,591	43,111	42,554
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	10	199	161

Potentially dilutive shares excluded from the calculation above represent stock options when the combined exercise price and unrecognized stock-based compensation are greater than the average market price for the Company's common stock because their effect is anti-dilutive.

Note 8. Commitments and Contingencies

Leases

We lease administrative, research and development, sales and marketing and manufacturing facilities and certain equipment under various non-cancelable lease agreements. Facility leases generally provide for periodic rent increases, and may contain clauses for rent escalation, renewal options or early termination.

The components of lease expense and supplemental cash flow information related to leases during the respective periods are as follows (in thousands):

	Year ended December 31,	
	2020	2019
Finance lease ROU asset amortization	$ 303	$ 314
Finance lease interest expense	877	835
Total finance lease costs	1,180	1,149
Operating lease costs	11,236	10,130
Total lease costs	$ 12,416	$ 11,279
Cash paid for amounts included in the measurement of operating lease liabilities		
Operating cash flows from operating leases	$ 10,801	$ 9,385
Operating cash flows from finance leases	$ 877	$ 835
ROU assets obtained in exchange for new lease liabilities		
Operating leases	$ 15,271	$ 12,231
Finance leases	$ —	$ 1,369

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2020 are as follows (dollars in thousands):

Years ending December 31,	Operating	Finance
2021	$ 12,043	$ 1,215
2022	11,396	1,258
2023	11,281	1,277
2024	11,226	1,098
2025	11,327	1,019
Thereafter	79,893	12,420
Total lease payments	137,166	18,287
Less: imputed interest	(28,661)	(13,949)
Total	108,505	4,338
Less: current portion	(7,799)	(238)
Non-current portion	$ 100,706	$ 4,100
Weighted average remaining lease term	14.3 years	12.6 years
Weighted average discount rate	4 %	27 %

Summers Ridge Lease — The Company leases three of the four buildings that are located on the Summers Ridge Property in San Diego, California with an initial term through January 2033 with options to extend the lease for two additional five-year terms upon satisfaction of certain conditions, which have not been included in the determination of the lease term. The lease is subject to must-take provisions related to one additional building, which will have the same lease term as the three buildings originally leased. The remaining building is subject to the expiration of the lease with its current tenant for which the expiration date is not yet known.

McKellar Lease — During 1999, the Company completed a sale and leaseback transaction of its San Diego facility at McKellar Court to a partnership for which the Company is a 25% limited partner. The partnership is deemed to be a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not have the power to direct the activities of the partnership and does not have the obligation to absorb losses or receive benefits of the partnership that could potentially be significant to the partnership. The Company made lease payments to the partnership of approximately $1.0 million, $1.0 million and $0.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Rutherford Lease — During January 2021, the Company entered into a lease agreement for a manufacturing facility in Carlsbad, California. The minimum lease payments related to the lease is approximately $70.5 million. The initial lease term is 15 years with options to extend the lease for two additional five-year periods.

Purchase Commitments

The Company has $32.1 million in firm inventory purchase commitments as of December 31, 2020, the majority of which will be purchased within the next twelve months.

Litigation and Other Legal Proceedings

In Beckman Coulter Inc. v. Quidel Corporation, which was filed in the Superior Court for the County of San Diego, California, on November 27, 2017, Beckman Coulter ("Beckman") alleges that a provision of an agreement between Quidel and Beckman violates state antitrust laws. Our acquisition of the B-type Naturietic Peptide assay business ("BNP Business") consisted of assets and liabilities relating to a contractual arrangement with Beckman (the "Beckman Agreement") for the supply of antibodies and other inputs related to, and distribution of, the Triage® BNP Test for the Beckman Coulter Access Family of Immunoassay Systems. The Beckman Agreement further provides that Beckman, for a specified period, cannot research, develop, manufacture or sell an assay for use in the diagnosis of cardiac diseases that measures or detects the presence or absence of BNP or NT-pro-BNP (a related biomarker) (the "Exclusivity Provision"). In the lawsuit, Beckman asserts that this provision violates certain state antitrust laws and is unenforceable. Beckman contends that it has suffered damages due to this provision and seeks a declaration that this provision is void.

On December 7, 2018, the trial court granted a motion by Beckman for summary adjudication, holding that the Exclusivity Provision is void under California law (the "December 7 Order"). On December 18, 2018, the trial court stayed the effect of the December 7 Order pending a decision on a writ petition Quidel intended to file with the Court of Appeal. Quidel filed its writ petition on January 18, 2019, asking the Court of Appeal to review and reverse the December 7 Order. On February 7, 2019, the trial court stayed all the remaining litigation pending the outcome of the writ petition and vacated all deadlines in the case.

On March 14, 2019, the Court of Appeal issued an order to show cause why the relief sought in Quidel's petition should not be granted. The Court also stayed the December 7 Order pending a further order from the Court of Appeal. On August 29, 2019, the Court of Appeal issued a written decision ruling in Quidel's favor and overturning the December 7 Order. Beckman challenged the Court of Appeal's ruling with a petition for rehearing on September 10, 2019, which was denied on September 13, 2019.

On October 1, 2019, Beckman filed a petition for review of the Court of Appeal's ruling with the Supreme Court of California (the "Supreme Court"). We subsequently filed an answer to Beckman's petition, Beckman filed a response to our reply and on November 13, 2019, the Supreme Court granted review of the Court of Appeal ruling, with further action in this matter being deferred pending consideration and disposition of a related issue in *Ixchel Pharma v. Biogen*, or pending further order of the Supreme Court.

On August 3, 2020, the Supreme Court issued its opinion in *Ixchel Pharma v. Biogen*, holding, among other matters, that in evaluating whether a restraint in a business-to-business agreement violates California law, "a rule of reason applies to determine the validity of a contractual provision by which a business is restrained from engaging in a lawful trade or business with another business." That is, the Supreme Court rejected the position that every contract in restraint of trade in the business context is per se void, but rather each must be evaluated based on a rule of reason.

On September 9, 2020, the Supreme Court transferred the matter back to the Court of Appeal with directions to vacate its decision and reconsider the case in light of the Supreme Court's *Ixchel Pharma v. Biogen* ruling.

On November 6, 2020, the Court of Appeal issued its opinion, granting our petition and directing the trial court to vacate its December 7, 2018 order granting Beckman's motion for summary adjudication.

On January 20, 2021, the Court of Appeal issued a remittitur, certifying its November 6, 2020 opinion and transferring the case back to the trial court where the litigation will continue and the exclusivity provision will be evaluated under a rule of reason analysis under California law.

The stay remains in place at the trial court level and a status conference is scheduled for March 12, 2021.

Quidel denies that the Exclusivity Provision is unlawful, denies any liability with respect to this matter, and intends to vigorously defend itself. There are multiple factors that prevent us from being able to estimate the amount of loss, if any, that may result from this matter including: (1) we are vigorously defending ourselves and believe that we have a number of meritorious legal defenses; (2) there are unresolved questions of law and fact that could be important to the ultimate resolution of this matter, some of which are subject to review by the Supreme Court; and (3) discovery is ongoing. Accordingly, at this time, we are not able to estimate a possible loss or range of loss that may result from this matter or to determine whether such loss, if any, would have a material adverse effect on our financial condition, results of operations or liquidity.

From time to time, the Company is involved in other litigation and proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to our business. The Company accrues for legal claims when, and to the extent that, amounts associated with the claims become probable and are reasonably estimable. The actual costs of resolving legal claims may be substantially higher or lower than the amounts accrued for those claims. For those matters as to which we are not able to estimate a possible loss or range of loss, we are not able to determine whether the loss will have a material adverse effect on our business, financial condition or results of operations or liquidity. No accrual has been recorded as of December 31, 2020 and December 31, 2019 related to such matters as they are not probable and/or reasonably estimable.

Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. However, the resolution of, or increase in any accruals for, one or more matters may have a material adverse effect on the Company's results of operations and cash flows. The Company also maintains insurance, including coverage for product liability claims, in amounts that management believes are appropriate given the nature of its business.

Licensing Arrangements

The Company has entered into various licensing and royalty agreements, which largely require payments by the Company based on specified product sales as well as the achievement of specified milestones. The Company had royalty and license expenses relating to those agreements of approximately $2.4 million, $1.1 million and $0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 9. Segment, Revenue and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 13%, 33% and 32% of total revenue for the years ended December 31, 2020, 2019 and 2018, respectively, of which sales to customers in China comprised 4%, 13% and 10%, respectively. As of December 31, 2020 and 2019, net accounts receivable due from foreign customers were $18.6 million and $22.9 million, respectively. For the year ended December 31, 2020, sales of our coronavirus products accounted for 70% of total revenue. For the years ended December 31, 2020, 2019 and 2018, sales of our influenza products accounted for 8%, 26%, and 24% respectively, of total revenue.

The Company had sales to individual customers in excess of 10% of total revenue, as follows:

	Year ended December 31,		
	2020	2019	2018
Customer:			
A	29 %	13 %	12 %
B	16 %	18 %	19 %
C	13 %	5 %	5 %
D	10 %	15 %	13 %
	68 %	51 %	49 %

As of December 31, 2020 and 2019, net accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $411.7 million and $53.5 million, respectively.

The following presents long-lived assets (excluding intangible assets) and total net revenue by geographic territory (in thousands):

	Long-lived assets as of December 31,		Total revenue for the years ended December 31,		
	2020	2019	2020	2019	2018
Domestic	$ 108,375	$ 78,254	$ 1,452,329	$ 358,381	$ 354,895
Foreign	2,106	1,508	209,339	176,509	167,390
Total	$ 110,481	$ 79,762	$ 1,661,668	$ 534,890	$ 522,285

Consolidated total revenues by product category are as follows (in thousands):

	Year ended December 31,		
	2020	2019	2018
Rapid Immunoassay	$ 1,144,831	$ 191,736	$ 183,160
Cardiometabolic Immunoassay	242,933	266,505	266,524
Molecular Diagnostic Solutions	222,964	21,716	19,358
Specialized Diagnostic Solutions	50,940	54,933	53,243
Total revenues	$ 1,661,668	$ 534,890	$ 522,285

Note 10. Fair Value Measurement

The following table presents the Company's hierarchy for its assets and liabilities measured at fair value on a recurring basis as of the following periods (in thousands):

	December 31, 2020				December 31, 2019			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents (money market funds)	$200,003	$ —	$ —	$200,003	$ —	$ —	$ —	$ —
Derivative assets	—	24	—	24	—	321	—	321
Total assets measured at fair value	$200,003	$ 24	$ —	$200,027	$ —	$ 321	$ —	$ 321
Liabilities:								
Derivative liabilities	$ —	$ 3,061	$ —	$ 3,061	$ —	$ 433	$ —	$ 433
Contingent consideration	—	—	11,896	11,896	—	—	16,535	16,535
Deferred consideration	—	115,951	—	115,951	—	151,382	—	151,382
Total liabilities measured at fair value	$ —	$119,012	$ 11,896	$130,908	$ —	$ 151,815	$ 16,535	$168,350

There were no transfers of assets or liabilities between Level 1, Level 2, and Level 3 categories of the fair value hierarchy during the years ended December 31, 2020 and 2019.

Cash equivalents consistent of funds held in money market accounts that are valued using quoted prices in active markets for identical instruments. Derivative financial instruments are based on observable inputs that are corroborated by market data. Observable inputs include broker quotes and daily market foreign currency rates and forward pricing curves.

In connection with the acquisition of the BNP Business, the Company pays annual installments of $42.0 million each in deferred consideration through April 2023 and up to $8.0 million each in contingent consideration through April 2022. The fair value of the deferred consideration is calculated based on the net present value of cash payments using an estimated borrowing rate based on a quoted price for a similar liability. The fair value of contingent consideration is calculated using a discounted probability weighted valuation model. Discount rates used in such calculation is a significant assumption that is not observed in the market and, therefore, the resulting fair value represents a Level 3 measurement.

The Company assesses the fair value of contingent consideration to be settled in cash related to these prior acquisitions using a discounted revenue model. Significant assumptions used in the measurement include revenue projections and discount rates. This fair value measurement of contingent consideration is based on significant inputs not observed in the market and thus represent Level 3 measurements. The changes in fair value of the contingent considerations during the years ended 2020, 2019 and 2018 were due to changes in the estimated payments and discounting periods.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2017 through December 31, 2020 are as follows (in thousands):

	Contingent consideration liability (Level 3 measurement)
Balance at December 31, 2017	$ 24,301
Cash payments	(6,303)
Change in estimated fair value, recorded in general and administrative expenses	1,114
Balance at December 31, 2018	19,112
Cash payments	(4,044)
Change in estimated fair value, recorded in general and administrative expenses	1,467
Balance at December 31, 2019	16,535
Cash payments	(6,044)
Change in estimated fair value, recorded in general and administrative expenses	1,405
Balance at December 31, 2020	$ 11,896

Note 11. Employee Benefit Plan

The Company has a defined contribution 401(k) plan (the "401(k) Plan") covering all employees who are eligible to join the 401(k) Plan upon employment. Employee contributions are subject to a maximum limit by federal law. This Plan includes an employer match of 50% on the first 6% of pay contributed by the employee. The Company contributed approximately $3.1 million, $2.5 million and $2.6 million to the 401(k) Plan during the years ended December 31, 2020, 2019 and 2018, respectively.

Note 12. Foreign Currency Hedges

In the normal course of business, the Company is exposed to gains and losses resulting from fluctuations in foreign currency exchange rates. As part of its strategy to manage the level of exposure to the risk of fluctuations in foreign currency exchange rates, the Company uses designated cash flow hedges in the form of foreign currency forward contracts to mitigate the impact of foreign currency translation on transactions that are denominated primarily in the Euro and the Chinese Yuan. The Company also uses non-designated forward contracts to hedge non-functional currency denominated balance sheet assets. Hedging relationships for all derivative hedges and the underlying hedged items, as well as the risk management objectives and strategies for undertaking the hedge transactions are formally documented. The Company does not use any derivative financial instruments for trading or other speculative purposes.

Such forward foreign currency contracts are carried at fair value in prepaid expenses and other current assets or other current liabilities depending on the unrealized gain or loss position of the hedged contract as of the balance sheet date. Changes in the value of the derivatives are recorded to other comprehensive income (loss) until the underlying hedged item is recognized in earnings, or the derivative no longer qualifies as a highly effective hedge. The cash flows from derivatives treated as hedges are classified in the Consolidated Statements of Cash Flows in the same category as the item being hedged.

The notional principal amounts for outstanding derivative instruments provide one measure of the transaction volume outstanding and do not represent the amount of our exposure to credit or market loss. Credit risk represents our gross exposure to potential accounting loss on derivative instruments that are outstanding or unsettled if all counterparties failed to perform according to the terms of the contract, based on then-current currency exchange rates at each respective date. We generally enter into master netting arrangements, which reduces credit risk by permitting net settlement of transactions with the same counterparty. We present our derivative assets and derivative liabilities at their net fair values. We did not have any derivative instruments with credit-risk related contingent features that would require us to post collateral.

The following table summarizes the fair value and notional amounts of the foreign currency forward contracts as of December 31, 2020 and December 31, 2019 (in thousands):

	December 31, 2020		December 31, 2019	
	Notional Amount	Fair Value, Net	Notional Amount	Fair Value, Net
Designated cash flow hedges:				
Prepaid expenses and other current assets	$ —	$ —	$ 27,944	$ 321
Other current liabilities	$ 38,435	$ 2,819	$ 6,219	$ 433
Non-designated forward contracts:				
Prepaid expenses and other current assets	$ 18,160	$ 24	$ —	$ —
Other current liabilities	$ 23,120	$ 242	$ —	$ —

Note 13. Selected Quarterly Financial Data (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2020				
Total revenues	$ 174,653	$ 201,754	$ 476,058	$ 809,203
Gross profit	$ 114,991	$ 148,751	$ 383,619	$ 701,494
Operating income	$ 51,628	$ 83,663	$ 307,959	$ 617,076
Net income	$ 40,237	$ 67,652	$ 232,268	$ 470,130
Basic income per share	$ 0.96	$ 1.61	$ 5.52	$ 11.14
Diluted income per share	$ 0.93	$ 1.55	$ 5.33	$ 10.78
2019				
Total revenues	$ 147,968	$ 108,252	$ 126,492	$ 152,178
Gross profit	$ 90,927	$ 59,179	$ 75,859	$ 94,840
Operating income	$ 31,153	$ 5,818	$ 20,682	$ 35,063
Net income	$ 24,844	$ 1,270	$ 16,181	$ 30,626
Basic earnings per share	$ 0.63	$ 0.03	$ 0.39	$ 0.73
Diluted earnings per share	$ 0.60	$ 0.03	$ 0.38	$ 0.71

SCHEDULE II

QUIDEL CORPORATION

CONSOLIDATED VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at beginning of period	Additions charged to expense or as reductions to revenue (1)	Deductions (2)	Balance at end of period
		(in thousands)		
Year ended December 31, 2020:				
Accounts receivable allowance	$ 15,960	$ 276,988	$ (189,513)	$ 103,435
Year ended December 31, 2019:				
Accounts receivable allowance	$ 11,979	$ 65,649	$ (61,668)	$ 15,960
Year ended December 31, 2018:				
Accounts receivable allowance	$ 12,309	$ 65,142	$ (65,472)	$ 11,979

(1) Primarily represents charges for contract rebate allowances recorded as reductions to revenue. Additions to allowance for doubtful accounts are recorded to sales and marketing expense.
(2) The deductions represent actual charges against the accrual described above.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures: We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2020 at a reasonable assurance level to ensure that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control over financial reporting: There was no change in our internal control over financial reporting during the quarter ended December 31, 2020 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's report on internal control over financial reporting: Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which is included in this Item 9A.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Quidel Corporation

Opinion on Internal Control over Financial Reporting

We have audited Quidel Corporation's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Quidel Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and schedule listed in the Index at Item 15(a)(2) and our report dated February 18, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 18, 2021

Item 9B. Other Information

2021 Annual Meeting of Stockholders

The Company's 2021 Annual Meeting of Stockholders will be held on Tuesday, May 18, 2021, beginning at 8:30 a.m., Pacific Time. The Annual Meeting will be held virtually and can be accessed online.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our 2021 proxy statement, which will be filed with the SEC no later than April 30, 2021 (the "2021 Proxy Statement"). Information with respect to the Company's executive officers is included under Part 1 of this Annual Report.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from our 2021 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from our 2021 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from our 2021 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from our 2021 Proxy Statement.

Part IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Form 10-K:

(a) (1) Financial Statements

The Consolidated Financial Statements required by this Item are submitted in Part II, Item 8 of this Form 10-K.

(2) Financial Statement Schedules

The following Financial Statement Schedule of Quidel Corporation for the years ended December 31, 2020, 2019 and 2018 is submitted in Part II, Item 8 of this Form 10-K and should be read in conjunction with the Consolidated Financial Statements of Quidel Corporation:

Schedule II. Consolidated Valuation and Qualifying Accounts.

Financial Statement Schedules not listed above have been omitted because of the absence of conditions under which they are required or because the required information is included in the Consolidated Financial Statements or the Notes thereto.

(3) Exhibits. See Paragraph 15(b) below.

(b) Exhibits

The Exhibit Index immediately following this Item 15 is filed as part of, and incorporated by reference into, this Annual Report on Form 10-K.

(c) Financial Statements required by Regulation S-X which are excluded from this Annual Report on Form 10-K by Rule 14(a)-3(b).

Not applicable.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of Quidel Corporation, effective as of May 5, 2015. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 6, 2015.)
3.3	Amended and Restated Bylaws of Quidel Corporation, as of November 9, 2020. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on November 13, 2020.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.)
4.2	Specimen stock certification. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 filed on August 31, 2010.)
4.3	Description of Quidel Corporation's Securities Registered Pursuant to Section 12 of the Exchange Act of 1934. (Incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K for the year ended December, 31 2019.)
10.1(1)	Registrant's Amended and Restated 1983 Employee Stock Purchase Plan. (Incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 14, 2016.)
10.2(1)	Registrant's Amended and Restated 2018 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 12, 2018.)
10.3(1)	Form of Notice of Grant of Award and Award Agreement for Registrant's 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.4(1)	Form of Restricted Stock Award Agreement for Registrant's 2010 Equity Incentive Plan. (Incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 filed on May 14, 2010.)
10.5(1)	Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on April 14, 2016.)
10.6(1)	Form of Notice of Grant of Stock Options and Option Award Agreement for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016.)
10.7(1)	Form of Restricted Stock Unit Award Grant Notice for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016.)
10.8(1)	Form of Restricted Stock Unit Award Grant Notice (Deferred Compensation) for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016.)
10.9(1)	Form of Restricted Stock Unit Award Terms and Conditions for Registrant's 2016 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016.)
10.10	Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 8-K filed on January 4, 2000.)
10.11	Second Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed on December 29, 2009.)
10.12	Third Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.10 to Registrant's Annual Report on Form 10-K filed for the year ended December 31, 2015.)
10.13(1)	Form of Indemnification Agreement – Corporate Officer and/or Director (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 13, 2020.)

10.14(1)	Employment Agreement, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 20, 2009.)
10.15(1)	Agreement Re: Change in Control, dated as of January 16, 2009, between the Registrant and Douglas C. Bryant. (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on January 20, 2009.)
10.16(1)	Employment Offer Letter, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 6, 2008.)
10.17(1)	Agreement Re: Change in Control, entered into on June 5, 2008, between the Registrant and Robert J. Bujarski. (Incorporated by reference to Exhibit 10.2 to Registrant's Form 8-K filed on June 6, 2008.)
10.18(1)	Randall Steward Employment Offer Letter, dated as of September 12, 2011. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 21, 2011.)
10.19(1)	Agreement Re: Change in Control, dated as of September 19, 2011, between the Registrant and Randall Steward. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 21, 2011.)
10.20(1)	Employment Offer Letter, dated April 24, 2014, between the Registrant and Werner Kroll. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.21(1)	Agreement Re: Change in Control, entered into on May 9, 2014, between the Registrant and Werner Kroll. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.22(1)	Employment Offer Letter, dated October 4, 2015, between the Registrant and Edward K. Russell. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.)
10.23(1)	Agreement Re: Change in Control, entered into on October 12, 2015, between the Registrant and Edward Russell. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.)
10.24	Amended and Restated Triage Purchase Agreement, dated September 15, 2017. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 6, 2017.)
10.25	Amended and Restated BNP Purchase Agreement, dated September 15, 2017. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 6, 2017.)
10.26	Summers Ridge Lease. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 9, 2018.)
10.27(1)	Agreement Re: Change in Control, entered into on February 11, 2019, between the Registrant and Karen Gibson. (Incorporated Agreement Re: Change in Control, entered into on February 11, 2019, between the Registrant and Karen Gibson. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.) reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.)
10.28	Amended and Restated Credit Agreement, by and among Company, as Borrower, Bank of America, N.A.as Administrative Agent, Swing Line Lender and L/C Issuer, JPMorgan Chase Bank, N.A., as Syndication Agent, Bank Of America Merrill Lynch and JP Morgan Chase Bank, N.A., as Joint Lead Arrangers and Joint Lead Bookrunners, dated as of August 31, 2018. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.)
10.29(1)	Form of Restricted Stock Unit Award Grant Notice. (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.).
10.30(1)	Form of Restricted Stock Unit Award Grant Notice. (Performance Based) (Incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.).
10.31(1)	Form of Restricted Stock Unit Award Grant Notice. (Time Based) (Incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.).
10.32(1)	Form of Notice of Grant of Nonqualified Stock Options and Option Agreement. (Incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.).
10.33(1)	Form of Restricted Stock Unit Award Grant Notice. (Deferred) (Incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.).
10.34(1)	2019 Annual Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on February 6, 2019.)

10.35(1)	2020 Cash Incentive Compensation Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 5, 2020.)
10.36(1)	2020 Annual Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on February 5, 2020.)
10.37(1)	Individual Retirement Program for Randall Steward. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 22, 2019.)
10.38(1)	Individual Retirement Program for Werner Kroll. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on February 4, 2020.)
10.39	Fourth Amendment to Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.)
10.40	Amendment No. 1 to Amended and Restated Credit Agreement dated September 11, 2020. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.)
10.41(1)	Agreement Re: Change in Control, entered into on October 22, 2020 between the Registrant and Tammi Ranalli. (Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.)
10.42(1)	Agreement Re: Change in Control, entered into on October 22, 2020 between the Registrant and William Ferenczy. (Incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.)
10.43*	Lease Agreement by and between ARE-SD Region No. 71, LLC, a Delaware limited liability company, as Landlord and Quidel Corporation, a Delaware corporation, as Tenant Dated as of January 14, 2021.
10.44(1)	2021 Cash Inventive Compensation Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 5, 2020.)
10.45(1)	2021 Annual Equity Incentive Plan Grants to the Registrant's Executive Officers. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on February 5, 2020.)
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification by Principal Executive Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Principal Financial and Accounting Officer of the Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications by Principal Executive Officer and Principal Financial and Accounting Officer of the Registrant pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (v) Consolidated Statements of Stockholders' Equity (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (included as Exhibit 101).

* Filed / furnished herewith

(1) Indicates a management plan or compensatory plan or arrangement.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

QUIDEL CORPORATION

By /s/ DOUGLAS C. BRYANT

Douglas C. Bryant
President, Chief Executive Officer
(Principal Executive Officer)

Date: February 18, 2021

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ DOUGLAS C. BRYANT Douglas C. Bryant	Director, President, Chief Executive Officer (Principal Executive Officer)	February 18, 2021
/s/ RANDALL J. STEWARD Randall J. Steward	Chief Financial Officer, (Principal Financial and Accounting Officer)	February 18, 2021
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 18, 2021
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 18, 2021
/s/ KATHY P. ORDOÑEZ Kathy P. Ordoñez	Director	February 18, 2021
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 18, 2021
/s/ ANN D. RHOADS Ann D. Rhoads	Director	February 18, 2021
/s/ CHARLES P. SLACIK Charles P. Slacik	Director	February 18, 2021
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 18, 2021
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 18, 2021

[This page intentionally left blank]

[This page intentionally left blank]

QUIDEL SENIOR MANAGEMENT

Douglas C. Bryant
President and Chief Executive Officer

Randall J. Steward
Chief Financial Officer

Robert J. Bujarski
Chief Operating Officer

Michael D. Abney, Jr.
SVP, North American Sales & Distribution

Ratan S. Borkar
SVP, International Commercial Operations

William J. Ferenczy
SVP, Cardiometabolic Business Unit

Karen C. Gibson
SVP, Information Systems and Business Transformation

Michelle A. Hodges
SVP, General Counsel

Werner Kroll, Ph.D.
SVP, Research & Development

Tamara Ranalli
SVP, Molecular Business Unit

Edward K. Russell
SVP, Business Development

BOARD OF DIRECTORS

Kenneth F. Buechler, Ph.D.
Chairman of the Board, Quidel
Founder, Former President and CSO, Biosite Inc.

Douglas C. Bryant
President and Chief Executive Officer, Quidel Corporation

Edward L. Michael
Managing Partner and Co-Founder of LionBird Ventures

Kathy P. Ordoñez
Former Officer of Pacific Biosciences, RainDance Technologies, Inc., Quest Diagnostics, Inc., Celera and Hoffmann-La Roche

Mary Lake Polan M.D., Ph.D., M.P.H.
Clinical Professor, Yale University School of Medicine

Ann D. Rhoads
Former Chief Financial Officer, Forty Seven, Inc.

Charles P. Slacik
Former Senior Vice President and Chief Financial Officer for Beckman Coulter, Inc.

Matthew W. Strobeck, Ph.D.
Managing Partner of Birchview Capital

Kenneth J. Widder, M.D.
Former General Partner, Lattrell Venture Partners, LVP Life Sciences Ventures

Joseph D. Wilkins Jr.
Partner, TRG Healthcare

ANNUAL MEETING

The Annual Meeting of shareholders will be held as a virtual meeting at 8:30 a.m., Tuesday, May 18, 2021, and will be webcast at: www.virtualshareholdermeeting.com/QDEL2021

Outside Legal Counsel
Gibson, Dunn & Crutcher LLP
Irvine, California 92612

Snell & Wilmer, LLP
Phoenix, Arizona 85004

Independent Registered Public Accounting Firm
Ernst & Young LLP
San Diego, California 92121

Investor Relations
Ruben Argueta
9975 Summers Ridge Road
San Diego, California 92121 USA
858.646.8023
ruben.argueta@quidel.com

Stockholder Inquiries
Inquiries related to stock transfer or lost certificates should be directed to the Transfer Agent.

Transfer Agent & Registrar
AST Financial
59 Maiden Lane
Plaza Level,
New York, New York 10038
800.937.5449
www.astfinancial.com

Nasdaq Listing
Quidel common stock is traded on the Nasdaq Stock Market under the symbol "QDEL."

Form 10-K and Form 10-Q
A copy of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports that we file with the Securities and Exchange Commission are available without charge upon request. Please contact Investor Relations.

Quidel's annual, quarterly, periodic reports, press releases and other information are located on Quidel's web site: quidel.com

AR1000400EN00 (04/21)

CORPORATE HEADQUARTERS

Quidel Corporation Corporate Headquarters

9975 Summers Ridge Road
San Diego, California 92121 USA

U.S. Operations

San Diego, California • Athens, Ohio • Beverly, Massachusetts

International Operations

Canada • China • France • Germany • India • Ireland • Italy & Global Distribution