CHANGING LIVES

2021

ANNUAL REPORT

QUIDEL®

BIG. BOLD. BREATHTAKING.

QUIDEL

OFFICIAL DIAGNOSTICS PARTNER

"It took three big, bold and breathtaking transformative initiatives over the course of five years to get Quidel to where we are today."

On the cover: Adriana Gamboa, Director, R&D

Dear Fellow Shareholders,

Our company has emerged from yet another pandemic year in superb fiscal and cultural health. Our performance in 2021 was exceptional across the board – from our research labs to our facilities and operations to our finance and functional departments. Despite global supply disruptions and innumerable other challenges, the entire Quidel team remained united in mission, unrelenting in tenacity, and unshakeable in focus. The results of their achievements are fully detailed in this Annual Report, but I hope you will grant me the privilege of sharing my own observations on the year (and what lies ahead) with you here.

Quidel entered 2021 with considerable momentum, and throughout a hugely transformational year, we leveraged that energy to open new channels for sustainable, long-term growth on a global scale.

*Seemingly everything we did was **big**:* We opened our largest immunoassay manufacturing facility in just nine months; boosted output ten-fold to help meet demand; entered the retail and at-home testing channels with our QuickVue® At-Home OTC COVID-19 assays; created strategic partnerships with CVS, Walgreens, the NIH and others; and entered into a 12-month agreement with the U.S. government estimated at over $500 million in revenue.

*Much of what we did was **bold**:* Continuing to ramp up production of QuickVue and Sofia® rapid immunoassays when others were retrenching; overcoming supply chain challenges and production interruptions caused by positive COVID-19 cases within our workforce; launching our revolutionary Savanna® molecular diagnostic instrument system outside the United States; and signing a definitive agreement to acquire Ortho Clinical Diagnostics Holdings plc ("Ortho"), a transaction that we expect will double our size and more than double our addressable global market.

*And the sum of what we did was **breathtaking**:* Investing in manufacturing that multiplied our scope and scale, and positioned us for durable, high-margin growth; marking the highest revenue year in Quidel's history, surpassing an exceptionally high-growth 2020 revenue number; dramatically broadening the range of patients, partners and providers we serve; and emerging from a challenging year with the strongest portfolio of physical, financial and intellectual assets in our history.

It took three big, bold and breathtaking transformative initiatives over the course of five years to get Quidel to where we are today. The first came in 2017 when we acquired the Triage and Beckman BNP businesses from Alere, Inc. That transaction doubled the size of our organization at the time and extended our market leadership, adding an extensive cardiovascular and toxicology point-of-care offering to our innovative medical diagnostics portfolio. And through careful integration (that I will discuss later), we brought two strong organizations together, maximizing the best of each company and realizing the accretive synergies we envisioned.

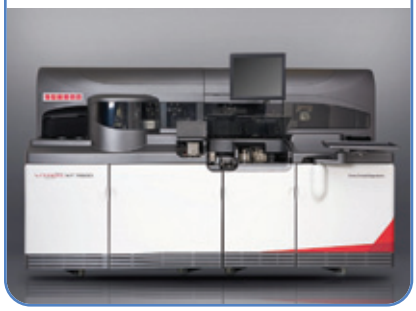
Our people's ability to execute during the COVID-19 pandemic was Quidel's second transformational initiative. The pandemic truly stress-tested every aspect of our company and our team. And, galvanized under a common purpose to help re-open America and its economy, our people responded with a torrent of diagnostic innovations and a relentless focus on manufacturing expansion that exponentially raised our production capacity and democratized access to the benefits of our assays. While this massive increase in production grew our top and bottom lines significantly, it also confirmed something more meaningful about our company: The tireless and nearly flawless performance of our people in pursuit of our mission to advance diagnostics and improve human health (in a time of great risk and uncertainty) proved that our professed purpose as a company is true, genuine, and authentic. Not only did we grow in size, but we also grew in

OUR MARKETS ARE SIGNIFICANT, OUR RUNWAY IS LONG

"We have the team, the strategic roadmap, and the can-do culture we call "The Quidel Way" to make the most of the opportunities we see ahead."

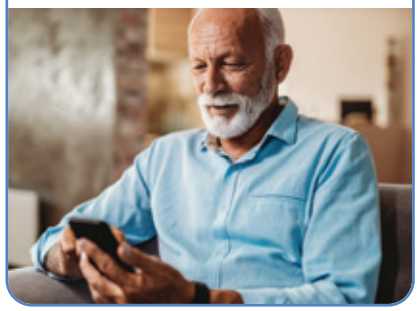
Savanna is a compact benchtop instrument that utilizes real-time PCR to deliver customizable, multiplexed, automated molecular results in minutes.

Extending point-of-care testing to include high-volume, high-complexity hospitals and labs.



Expanding further into retail and online entry points for consumer at-home testing.

Capture emerging markets through both telehealth technology and digital health capabilities.



spirit and showed the world the strength, resilience and dedication that is resident within our culture.

Our third transformation is our definitive agreement to acquire Ortho, which was announced in December of last year. The combination of Quidel and Ortho is expected to create an end-to-end diagnostics solutions portfolio that spans from the high-volume, high-complexity hospitals and labs to the farthest reaches of point-of-care and the vast untapped channels of retail, over-the-counter and the new frontiers of telemedicine. The transaction will give us the opportunity to extend Quidel's point-of-care testing to include clinical laboratories and transfusion medicine. The expected synergies of our and Ortho's complementary product portfolios, robust innovation pipelines and enhanced global reach position the combined company to substantially increase its global addressable market.

The net result of our transformative journey thus far is that our markets are significant, our runway is long, and as I describe further below, we have the team, the strategic roadmap, and the can-do culture we call "The Quidel Way" to make the most of the opportunities we see ahead.

Turning quickly to the numbers: On a full year basis, total revenue for 2021 increased to $1,699 million, a 2% increase from our previous high-water mark of $1,662 million in 2020. Our year-on-year revenue beat was primarily supported by strong demand for COVID-19 rapid immunoassay products for both Sofia and QuickVue. Growth in rapid immunoassays supported our performance for 2021, with QuickVue sales increasing exponentially. Including all our molecular lines – Lyra®, Solana® and Savanna – revenue for COVID-19 products in 2021 increased 42% to $1,267 million, from $891 million in 2020.

In 2021, we entered strategic partnerships with major retail names like CVS and Walgreens to further expand into the retail and online entry points for the consumer at-home testing channel. The uptake in both sales and brand recognition is building solid inroads for us to serve the retail sector, which we hope to participate in on a longer-term basis with a wider menu of offerings, including flu, strep, and other tests.

Our acceleration of assay development and production has also served to broaden our footprint at the point of care, helping drive introduction of our full portfolio to new groups of highly engaged patients and providers. Our pipeline has never been larger: Pre-COVID, we were working on about 20-30 R&D projects; today, we are managing over 50. For example, there continues to be a vast opportunity to capture demand in emerging markets through both telehealth technology and digital health capabilities, expanding patient access to a broad range of point-of-care and over-the-counter diagnostic products. In this new "tele-diagnostics" space, we have Sofia Q, as well as a recently launched mobile application for monitored self-testing that we call "QVue™ Business" to help address enterprise and employee health use cases. We have a consumer version of the app in development as well.

As part of our focus on democratizing access to testing, we take considerable pride in the fact that we supported financially or donated a portion of our COVID-19 testing production to charitable organizations such as the United Way, the Jets Foundation, University of Arizona, the Chicano Federation of San Diego and the Blackhawks Foundation through our academic, government and sports league partners. Our charitable partnerships helped serve some of the communities hit hardest by COVID-19 and we are proud to have played a part in increasing equitable access to diagnostic testing.

The net result of our transformative journey thus far is that our markets are significant, our runway is long, and as I describe further below, we have the team, the strategic roadmap, and the can-do culture we call "The Quidel Way" to make the most of the opportunities we see ahead.

During 2021, we also announced the transition of the Beckman BNP business to Beckman Coulter, Inc. ("Beckman"), concluding the litigation that had been ongoing since the purchase of the business in October 2017. This agreement is a major step forward for both Quidel and Beckman. It enables us to focus on expanding our core businesses and executing on our longer-term strategy, while also establishing a stable cash flow stream of between $70 million and $75 million per year for Quidel through 2029, which is the remainder of the term of the existing BNP Supply Agreement.

Further to the subject of future cash flow streams, we made incredible progress with our revolutionary Savanna platform in 2021, launching the platform in the E.U. and actively preparing for its U.S. launch later this year. The Savanna platform will be our next flagship product. It allows for PCR testing of up to 12 pathogens plus controls from a single sample. The amplification time is very fast with total turnaround time for our respiratory viral panel ("RVP") in approximately 20 minutes. The Savanna platform is fully integrated, very easy to use and will have both direct swab and liquid sample compatibility. The reagent is stable at room temperature, which is a huge deal, particularly in the hospital labs.

As I mentioned above, we have already launched in the E.U. We are in-market in a limited launch with our RVP4 assay and have received very positive customer feedback to date, including requests for additional instruments. We expect 2022 to be a busy year for Savanna, as we work toward Emergency Use Authorization for RVP4 and a 510(k) submission for our RVP11 assay, as well as for our HSV/VZV, STI and gastrointestinal panels. We also plan on automating our U.S.-based manufacturing lines, thereby substantially increasing our production capacity for our Savanna cartridges once launched in the United States.

We are targeting Savanna platform revenues of over $300 million per year within three years of U.S. launch. Much of that will be determined by our ability to manufacture instruments and fully automate cartridge manufacturing lines. But if we have demonstrated anything during this pandemic, it is that we can scale rapidly, which bodes well for a flawless, successful launch.

Aside from our team's extraordinary execution and scaling our operations to help meet demand for COVID-19 testing, our biggest highlight of 2021 came at the very end of the year with the announcement of our agreement to acquire Ortho. We believe this transformative acquisition will position Quidel as a global leader in diagnostics, substantially diversifying our product pipeline while widening our global commercial reach and scale. Our agreement to acquire Ortho for a combination of cash and newly issued shares in the combined company is expected to make us one of the larger, pure play diagnostic companies in the industry.

Bringing our two leading companies together will give us the ability to leverage complementary expertise and an unparalleled range of capabilities to drive growth into new markets. The highly complementary nature of Quidel's and Ortho's product portfolios is expected to create ample cross-selling opportunities across a diverse customer and channel mix, enabling us to maximize the value of existing platforms and drive worldwide growth. Future revenue synergies are particularly attractive for Savanna, given Ortho's deep roots among laboratory customers and extensive global commercial reach. Driving global commercial execution of Savanna will be a chief priority for us in 2022 and beyond.

The planned Ortho acquisition is expected to more than double our global market opportunity, estimated to be worth over $50 billion between the point-of-care, clinical-chemistry and transfusion-medicine categories. Financially, it allows us to maintain 9% to 11% topline growth post-COVID and generate 30% or more EBITDA margins and substantial operating cash flow, creating a pathway for strong value creation over the long-term.

We launched the Savanna platform in the E.U., and are actively preparing for its U.S. launch later this year.

We are in-market in a limited launch with our RVP4 assay and have received very positive customer feedback.

Driving global commercial execution of Savanna will be a chief priority in 2022 and beyond.

DRIVING OUR BUSINESS FORWARD

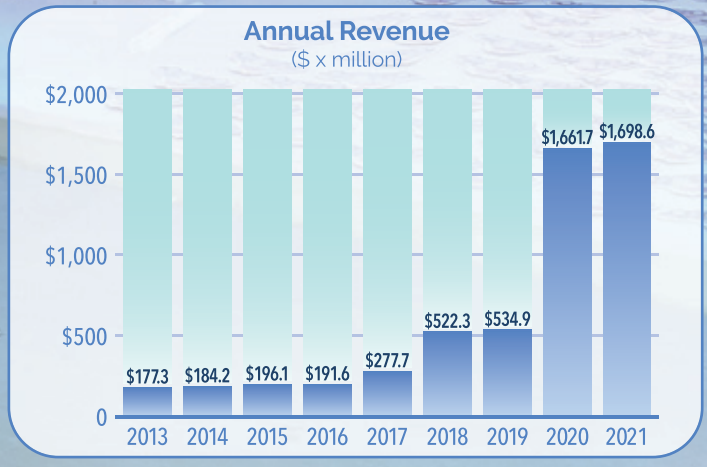
"Our acceleration of assay development and production has also served to broaden our footprint at the point of care, helping drive introduction of our full portfolio to new groups of highly engaged patients and providers."

CHANGING LIVES

On the line at the Rutherford plant.
Tony Infante, Tim Trejo, Alex Morelice

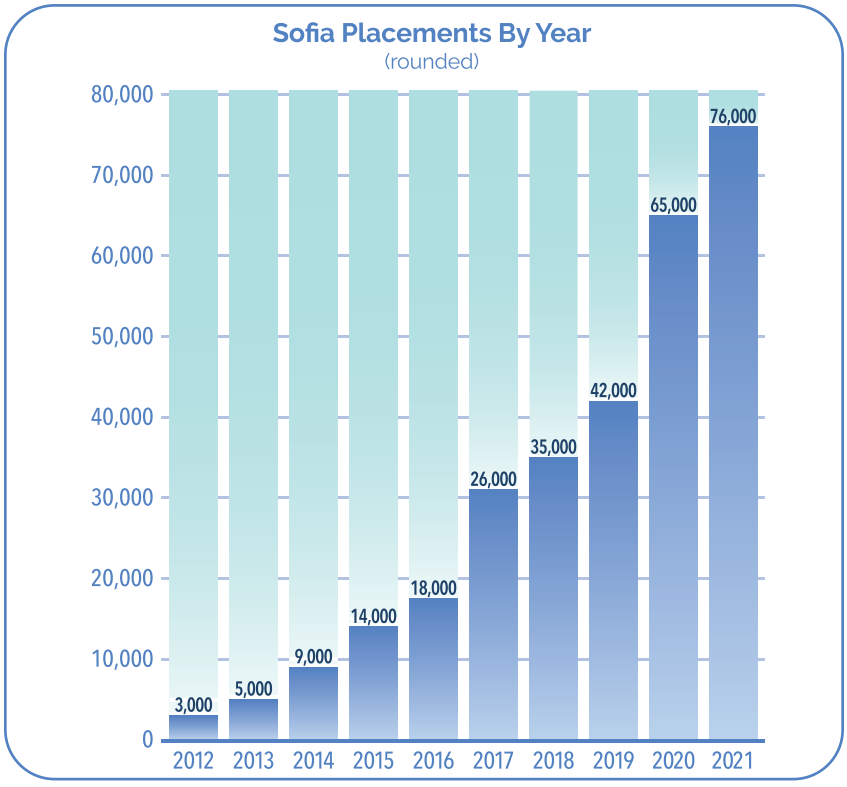
DEMOCRATIZING ACCESS TO TESTING

"Our charitable partnerships helped serve some of the communities hit hardest by COVID-19 and we are proud to have played a part in increasing equitable access to diagnostic testing."



Culturally, Quidel and Ortho are an excellent fit, which was a key factor in our decision to move forward with the acquisition. Both companies share a passion for advancing innovation and enhancing the well-being of the customers, patients and communities we serve. Of course, we are already hard at work setting the stage for a smooth integration. With our proven experience at successfully integrating acquired businesses into our operations, we are confident we have the right processes in place, and with the help of the great people at Ortho, we believe that we will achieve the milestones we have set for ourselves once integration plans can be implemented post-closing.

For a bit of background, our integration approach will be similar to the process we used to integrate the Alere assets, our first transformative event that doubled the size of our organization at the time. In some ways, that acquisition presented a more technically challenging integration. It was a carve-out asset purchase that did not include international entities and required a lengthy, staged, deferred closing process throughout the world over a couple years. We also spent a significant amount of time understanding the Alere culture, how the Triage product was manufactured and sold, and the ins and outs of the Beckman BNP business. So, we devoted a lot of energy to finding the right integration structure and working collaboratively with our new colleagues and third-party integration specialists to plan for a successful integration. It was essential for us to get it right. In the end, we harvested about $20 million in synergies from a $250 million set of businesses in a little over two years, and significantly de-levered from over 4-times leverage to under 1-time. We also improved the company morale, which had been under-prioritized, in our view. Given this experience and outcome, we believe we have a good system in place that is thoughtful, effective and reproducible.



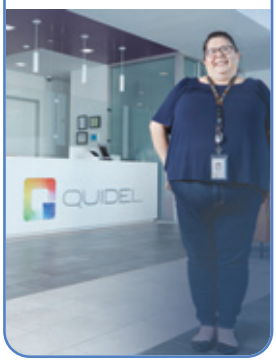
Our view is that Ortho is a great company with very talented employees, strong processes and a positive, customer-centered culture. We believe that both Ortho and Quidel can learn from each other and are taking a truly collaborative approach. We have appointed integration planning leaders on both the Quidel and Ortho sides, who are aided by exceptional third-party integration specialists, as well as a select team of employees from both organizations that is focused on driving a successful integration.

We have identified $90 million in expected cost synergies that we think are achievable within three years. These cost synergies are driven by operational efficiencies, supply chain optimization and shared administrative functions, including duplicative public company costs. Further, we have identified $100 million in expected revenue synergies by 2025, with approximately 80% to come from cross-selling opportunities and our expanded geographical footprint to sell Savanna and other products in markets outside the United States.

Our integration teams are working well together planning the integration, and I believe that shortly after closing, we will begin harvesting synergies, paying down debt, growing both businesses and bringing together two remarkable organizations. In addition, Chris Smith, Ortho's Chairman and Chief Executive Officer, will be joining me as a special advisor to utilize his experience and expertise to assist me in thinking through things that we know we will need to address, as well as those that are unknown at this time.

Based on our current expectations, we anticipate holding a special meeting for

Estella Calles, Receptionist/HR Assistant, Summers Ridge



Katherine Cruz, Production Lead and Tim Trejo, Equipment Maintenance Tech at Rutherford

Damian Whittemore, Manufacturing Engineer, Rutherford

stockholders to vote on the acquisition and expect it to close in the first half of the year. The completion of the acquisition is subject to certain closing conditions, but the good news is that the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act expired with respect to the acquisition on February 9, 2022. Post-closing, we anticipate the integration will be complete within approximately two years.

In closing, I am enormously proud of our accomplishments in 2021 and want to thank our entire Quidel team for the courage, creativity and resilience they showed personally and collectively in driving our business forward amid all of the challenges of the second pandemic year. Their steadfast commitment to our mission of advancing diagnostics to improve human health is responsible for our success as a company and as an impactful corporate citizen when our contributions mattered most. We look forward to driving further operational excellence in 2022 through strong execution against our growth roadmap. As we work to support our customers, partners and patients beyond the threat of COVID-19, we see great opportunities that lie ahead for Quidel to grow our core business and advance our diagnostics portfolio to improve the quality of healthcare and health outcomes across the globe.

With the U.S. launch of Savanna and the planned Ortho acquisition, we have many great opportunities to continue accelerating our growth throughout 2022 and beyond. I am excited to see our company further transform into a leading diagnostics player as we execute on those opportunities to enhance our competitive positioning and create long-term shareholder value.

Sincerely,

Douglas C. Bryant

President and CEO
Quidel Corporation
April 2022

As we work to support our customers, partners and patients beyond the threat of COVID-19, we see great opportunities that lie ahead for Quidel to grow our core business and advance our diagnostics portfolio to improve the quality of healthcare and health outcomes across the globe.

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, 2021

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 $4,581,300,641 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 11, 2022, 41,778,613 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None

QUIDEL CORPORATION

FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2021

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A Warning About Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). For this purpose, any statements contained herein that are not statements of historical fact, including without limitation certain statements under Part I, Item 1, "Business," Part I, Item 1A, "Risk Factors," and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and located elsewhere herein regarding industry prospects and our results of operations or financial position, may be deemed to be forward-looking statements. Without limiting the foregoing, the words "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words are intended to identify forward-looking statements. Our business is subject to a number of risks, including those discussed under Part I, Item 1A, "Risk Factors," that could cause actual results to differ materially from those indicated by forward-looking statements made herein and presented elsewhere by management from time to time. Such forward-looking statements represent management's current expectations and are inherently uncertain. Investors are warned that actual results may differ from management's expectations.

Summary of Risk Factors

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, which include, among others:

Operational and Strategic Risks

- the impact of the COVID-19 global pandemic;
- competition;
- our development of new technologies, products and markets;
- our reliance on sales of our COVID-19 and influenza diagnostic tests;
- our reliance on a limited number of key distributors;
- the financial soundness of our customers and suppliers;
- acceptance of our products among physicians, healthcare providers or other customers;
- the reimbursement system currently in place and future changes to that system;
- our ability to meet demand for our products and services;
- interruptions or shortages in the supply of raw materials and other components;
- costs and disruptions from failures in our information technology ("IT") and storage systems and our exposure to data corruption, cyber-based attacks, security breaches and privacy violations;
- interruptions to our third-party IT service providers and/or the inability of our digital solutions to interoperate with certain operating systems;
- international risks, including, but not limited to, compliance with product registration requirements, compliance with legal requirements, tariffs, exposure to currency exchange fluctuations, longer payment cycles, lower selling prices, greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, social, political and economic instability, increased financial accounting and reporting burdens and complexities, potentially adverse tax consequences, and diversion of lower priced international products into markets in the United States ("US");
- worldwide political and social uncertainty, including tariffs, trade wars or social tensions;
- natural disasters, public health crises, political crises and other catastrophic events;

Risks Related to Our Pending Business Combination

- completion of the Combinations (as defined herein) is uncertain and subject to certain conditions;
- failure to complete the Combinations could negatively impact our stock price and future business and financial results;
- the agreement governing the Combinations contains provisions that restrict our ability to pursue alternatives to the Combinations and could require us to pay a termination fee;
- we will incur significant costs in connection with the Combinations;
- we may have difficulty attracting, motivating and retaining executives and other key employees due to uncertainty associated with the Combinations;
- our business relationships may be subject to disruption due to uncertainty associated with the Combinations;
- completion of the Combinations may trigger change-in-control or other provisions in certain agreements that we are party to;

Intellectual Property Risks

- our development, acquisition and protection of proprietary technology rights;
- intellectual property risks, including, but not limited to, infringement and misappropriation claims;

Government and Regulatory Risks

- loss of our Emergency Use Authorization ("EUA") from the US Food and Drug Administration (the "FDA") for our COVID-19 products;
- failures or delays in the receipt of regulatory approvals, clearances or authorizations, the loss of previously received regulatory approvals, clearances or authorizations or other adverse actions by regulatory authorities;
- funding and compliance risks relating to government contracts, including the ability to meet key deliverables and milestones under our National Institute of Health ("NIH") RADx-ATP contract;
- product defects;
- compliance with government regulations relating to the handling, storage and disposal of hazardous substances;
- compliance with US federal, state and foreign privacy and data security laws and privacy requirements from our customers;
- changes in tax law relating to multinational corporations;

Risks Related to Our Acquisitions

- our ability to identify and successfully acquire and integrate potential acquisition targets;
- transitioning the BNP Business (as defined herein) to Beckman Coulter, Inc. ("Beckman") presents certain risks to our business and operations;

Corporate Finance Risks

- our need for additional funds to finance our capital or operating needs;
- our debt, deferred and contingent payment obligations could materially adversely affect our financial condition and results of operations;

General Risk Factors

- competition for and loss of management and key personnel;
- our exposure to claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us;
- business risks not covered by insurance;
- changes in tax rates and exposure to additional tax liabilities or assessments;
- certain provisions of our charter documents and Delaware law that may delay or impede stockholder actions with respect to business combinations or similar transactions; and
- failure to meet the expectations of investors and other stakeholders with respect to environmental, social and governance ("ESG") matters.

For a more complete discussion of these risk and uncertainties, see "Risk Factors" in Part I, Item 1A of this Annual Report.

Part I

Item 1. Business

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

Overview

Our primary mission is to advance diagnostics to improve human health. We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing 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, as well as for individual, non-professional, over-the-counter ("OTC") use. More recently, we have begun to reach significant new markets as we introduced our QuickVue® At-Home OTC COVID-19 test for reopening schools, and for health departments, employers, entertainment centers and many other locations. We market our products through a network of distributors and a direct sales force. We operate in one business segment that develops, manufactures and markets our products globally.

When we commenced our operations in 1979, we were originally incorporated as Monoclonal Antibodies, Inc. in the State of California. In 1987, we re-incorporated as Quidel Corporation in the State of Delaware. We launched our first products, dipstick-based pregnancy tests, in 1983. Since such time, our product base and technology platforms have expanded through internal research and 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.

In 2017, we acquired the Triage® MeterPro® cardiovascular and toxicology business ("Triage Business"), and B-type Natriuretic Peptide ("BNP") assay business run on Beckman analyzers ("BNP Business" and, together with the Triage Business, the "Triage and BNP Businesses") from Alere Inc. ("Alere"), which added an extensive cardiovascular and toxicology menu to our innovative medical diagnostics portfolio.

On December 22, 2021, we entered into a Business Combination Agreement (the "BCA") with Ortho, Coronado Topco, Inc. ("Topco"), Orca Holdco, Inc. ("US Holdco Sub") and Laguna Merger Sub, Inc. ("US Merger Sub"), each a wholly owned subsidiary of Topco, and Orca Holdco 2, Inc., a wholly owned subsidiary of US Holdco Sub ("US Holdco Sub 2"). Under the terms of the BCA, we are entering into a business combination with Ortho under Topco, a new holding company (the "Combinations"). Ortho will be acquired for total consideration of approximately $4.3 billion (which is based on the February 9, 2022 closing price of our common stock of $97.64 per share), including $1.75 billion of cash, funded through cash on our balance sheet and expected incremental borrowings. The Combinations are subject to approval by both our stockholders and Ortho's shareholders, as well as customary closing conditions and regulatory approvals. It is anticipated that the Combinations will close in the first half of 2022. For additional information about the Combinations, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments" in Part II, Item 7 of this Annual Report.

Our executive offices are located at 9975 Summers Ridge Road, San Diego, California 92121, and our telephone number is (858) 552-1100.

Product Categories

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

Our diagnostic testing solutions are separated into our four product categories: rapid immunoassay, cardiometabolic immunoassay, molecular diagnostic solutions and specialized diagnostic solutions. The products and platforms under each product category 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 received an EUA to market our 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. The QuickVue At-Home OTC COVID-19 test has also recently become a leading at-home COVID-19 product for home use and is available through many retail and online outlets.

InflammaDry and AdenoPlus. The InflammaDry and AdenoPlus products are rapid, lateral-flow based, point-of-care ("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 ("ACS"), and acute myocardial infarction ("AMI"), and can reduce hospital admissions and improve clinical and economic outcomes. Triage cardiovascular rapid tests include immunoassays for 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 US.

We have also offered a version of the Triage BNP test for use on Beckman lab analyzers historically, but have nearly completed the transition of this business to Beckman following entry into agreements with Beckman to resolve litigation between us and Beckman and provide for the transition of the BNP Business to Beckman. We will continue to supply Beckman products related to this business and will receive payments of between $70.0 and $75.0 million per year through 2029 under these arrangements.

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.

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.

Savanna. In late 2021, we launched in Europe our CE-Marked Savanna multiplex molecular analyzer system and Savanna RVP4 assay. The Savanna system is a low-cost, fully integrated, sample-to-result automated in vitro molecular diagnostic platform that enables analysis of up to 12 pathogens or targets, plus controls, from a single assay run in less than 25 minutes. The Savanna RVP4 assay is a rapid, multiplexed nucleic acid test intended for use with the Savanna instrument for the simultaneous qualitative detection and differentiation of influenza A, influenza B, respiratory syncytial virus ("RSV"), and SARS-CoV-2 RNA isolated from human nasal or nasopharyngeal swabs. We plan to launch the Savanna system in the US in 2022.

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 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 under the Quidel and MicroVue brands.

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. The Sofia SARS Antigen 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 POC test to be used with the Sofia 2 FIA 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 POC assay for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares swab specimens.

Lyra. Our Lyra SARS-CoV-2 assay and Lyra Direct SARS-CoV-2 assay are real-time Reverse Transcriptase-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-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 25 minutes.

Savanna. Our Savanna RVP4 assay is a rapid, multiplexed nucleic acid test intended for use with the Savanna instrument for the simultaneous qualitative detection and differentiation of influenza A, influenza B, RSV, and SARS-CoV-2 RNA isolated from human nasal or nasopharyngeal swabs.

Influenza. We offer a variety of products designed to detect the viral antigens of influenza type A and B utilizing FIA, 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 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 FIA, lateral flow and molecular technologies. Our Sofia Strep A and Strep A+ FIAs, 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 Streptococcal and for Strep Complete, also the detection of pyogenic Group C or G Streptococcal, 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 Group C or G Streptococcal throat infections.

RSV (and hMPV). Our Sofia RSV test and QuickVue RSV test are rapid immunoassay tests for RSV. In addition, we offer molecular testing options with our Solana RSV + human metapneumovirus ("hMPV") test and our combo Quidel Lyra RSV + hMPV test. The majority of upper respiratory tract infections in children are 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 direct fluorescent assays ("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 laboratories 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 hMPV 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 FDA clearance through a premarket notification or premarket approval ("510(k)") process and a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") from the FDA to market Sofia 2 Lyme FIA, which is used with the Sofia 2 FIA 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 Sofia 2 Lyme tests are intended for use with the Sofia 2 analyzer to aid in the diagnosis of Lyme disease in the US and European markets.

S. pneumoniae. Our Sofia S. Pneumoniae 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 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. Our Lyra Adenovirus assay is a real-time PCR test for the qualitative detection of human adenovirus ("HAdV") viral DNA, and our Lyra Parainfluenza assay is 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 has positioned us as a leader in this market for POC settings. 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 BNP in whole blood or plasma that aids in the diagnosis and assessment of severity of heart failure. The test is also used for the risk stratification of patients with ACS 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 that aids 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 ACS.

Triage D-Dimer Test. An immunoassay that aids 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 NT-proBNP in Ethylenediaminetetraacetic Acid ("EDTA") anticoagulated whole blood and plasma specimens. The test aids in the diagnosis of individuals suspected of having congestive heart failure. The test also aids in the risk stratification of patients with heart failure and 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 to aid 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 the troponin assay used for the quantitative determination of troponin I in whole blood and plasma specimens, anticoagulated with EDTA. It features a redesigned cartridge that greatly improves assay sensitivity and precision that are critical to the performance of high sensitivity troponin testing. The test aids in the diagnosis of MI.

Triage PLGF Test. An immunoassay that aids in the early and accurate diagnosis of preterm pre-eclampsia in pregnant women.

Triage BNP Test for Beckman Analyzers. We have also offered a version of our Triage BNP test for use on Beckman lab analyzers historically, but have nearly completed the transition of this business to Beckman.

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 US 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 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 FIA 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 to aid in the presumptive diagnosis of chlamydia. Chlamydia trachomatis is responsible for the most widespread sexually transmitted disease in the US. 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 GBS 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.

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 US and is more common in women.

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. 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 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. In addition, 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, is 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 H. pylori 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 determining the presence of drug and/or 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 urinary metabolites for multiple drug classes.

Digital and Telehealth Solutions

In 2022, Quidel introduced QVue Business, a mobile application that supports employee at-home testing using QuickVue At-Home OTC COVID-19 tests and a reporting system for employers to help track COVID-19 test results and trends within the workplace. The QVue Business application enables employees, contractors and other visitors to provide COVID-19 test results in near real time to employers. The application offers an at-home testing alternative to reduce the cost and effort of on-site testing and provides detailed videos to guide the user through the testing and reporting process. QVue Business is a flexible application that can be configured to an employer's desired testing frequency to track employees' symptoms or exposure risk and provide employees with a digital health passport for safe access into the workplace. Quidel plans to further expand its digital and telehealth solutions from the at-home testing, identity verification and reporting functions to the telehealth setting where patients can use Quidel's digital testing and reporting functions to further interact with healthcare professionals for diagnosis, treatment and care.

Connectivity and Data Management

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.

Business Strategy

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. In order to achieve our mission of advancing diagnostics to improve human health, our strategy is to do the following:

- focus on innovative products and markets and leverage our core competency in new medical and wellness 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 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;
  - 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 digital and telehealth solutions, including our mobile applications, to expand into healthcare markets;
- leverage our wireless connectivity and data management systems and capabilities, including cloud-based computing 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 POC 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.

Research and Development

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

- new proprietary product platform development,
- 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 $95.7 million, $84.3 million, and $52.6 million for the years ended December 31, 2021, 2020 and 2019, 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 to serve the continuum of healthcare delivery needs globally, starting with POC clinicians located in doctor's office practices, to moderately complex POLs, and to highly complex hospital and clinical reference laboratories in North America and a variety of settings internationally. We are also increasingly prioritizing retail and online outlets, such as large pharmacies, to market and distribute our QuickVue At-Home OTC COVID-19 tests. Within the inherent operational diversity of these various segments, we focus on differentiating ourselves and enhancing our market leadership by specializing in the diagnosis and monitoring of select disease states, conditions and wellness categories.

Our marketing strategy includes ensuring that our key product portfolios are supported by clinical validation and health economic and outcomes research that demonstrate 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 highly fragmented POC market, with many small or medium-sized customers. To reach customers using POC diagnostic tests, a network of national and regional distributors is employed, as well as our own sales force. We have expanded the size of our North America sales force in the past few years. As of December 31, 2021, we employed approximately 125 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. We reach laboratory end-users in hospitals and clinical reference laboratories using these diagnostic tests through our own direct sales force and technical support services that have specialized training and understanding of this product portfolio.

We sell products globally and market and distribute products worldwide in a variety of ways, including a mix of direct and indirect distribution strategies. In Europe, we currently employ approximately 95 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 60 employees in China and approximately 25 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, 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 49%, 68% and 51% of our total revenue for the years ended December 31, 2021, 2020 and 2019, respectively. See Note 9 to the Consolidated Financial Statements included in this Annual Report.

Manufacturing

We have five manufacturing sites. Two are in San Diego, California, one in Carlsbad, California, one in Athens, Ohio and one in Europe.

Our McKellar Court, San Diego, California, and our Carlsbad, California lateral flow manufacturing facilities consist 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. These facilities operate under a Quality Management System ("QMS") per International Organization for Standardization ("ISO") standard and regulatory regulations. These facilities are certified to ISO 13485:2016 and Medical Device Single Audit Program ("MDSAP") medical device standards. Many of the immunoassay products manufactured at these facilities are packaged and shipped by a local third party.

Our Athens, Ohio facility consists of a variety of clean room and chemistry laboratories, customized reagent 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 cell 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. This 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 this 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 this facility and are also supplied to a third party as key active ingredients for BNP products that run on Beckman analyzers. In addition, this facility 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 ISO 13485:2016 and MDSAP medical device standards. Most of the products are packaged and subsequently distributed by our San Diego distribution center.

Our facility in Europe conducts packaging, warehousing and shipping logistics with cold chain storage capability for Europe and the Middle East.

We seek to conduct our manufacturing in compliance with QMS regulatory requirements of the US, Australia, Brazil, Canada, Japan, Europe, South Korea and certain other countries. Our manufacturing facilities have passed routine regulatory inspections confirming compliance with the QMS regulatory requirements. Our facilities are registered with various regulatory bodies, including the FDA and the Department of Public Health of the State of California for our San Diego and Carlsbad facilities.

Competition

Competition in the development and marketing of *in vitro* diagnostic ("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 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 respiratory 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 and 2021. 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, 2021, 2020 and 2019, sales of our influenza products accounted for 4%, 8% and 26%, 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.

Government Regulations

US Regulations of Medical Devices

The testing, manufacture and commercialization of our products in the US are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state regulatory agencies. Pursuant to the US 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 US if the device is deemed to be unsafe.

In the US, 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, 510(k) clearance process 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 US 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 their safety or effectiveness or constitute a major change in the intended use of the device, will require new submissions to the FDA.

The FDA's CLIA regulate laboratory testing and requires clinical laboratories to be certified by their state, as well as the Centers for Medicare & Medicaid Services ("CMS"), before diagnostic testing can be conducted. Laboratories 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, which are onerous and have increased the time and cost we are required to spend 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 Quidel System Regulations relating to testing, control, documentation and other quality assurance requirements. We must also comply with Medical Device Reporting requirements, which mandates 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 ("FTC"). Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

Regulations Outside of the US

For marketing outside the US, 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 US, 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 varies from 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 US is typically in the European Union ("EU"), Australia, Brazil, Canada, China, and Japan. EU regulations and directives generally classify healthcare products either as medicinal products, medical devices or IVD. The CE Mark certification for the EU requires us to receive certification from ISO for the manufacture of our products. 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 that attests to the product's compliance to Regulation Directive 98/79/EC for IVD 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 than in the US, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The compliance deadline for the EU MDR was May 2021. Manufacturers of currently approved medical devices will have until May 2022 to meet the EU IVDR, unless an extension has been granted. Complying with these regulations may require us to incur significant expenditures. Failure to meet these regulatory 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 IVD 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. IVD products in Brazil are regulated by the Agencia Nacional de Vigilancia Sanitaria. For our products marketed in Canada, Japan, Brazil, Australia and the US, the MDSAP is a single regulatory audit of our QMS that satisfies the requirements of all five of these jurisdictions. Additionally, with Brexit in place, we are obtaining any necessary approvals directly from the U.K.'s Medicines and Healthcare Products Regulatory Agency.

Other Healthcare Laws

Our products are subject to various healthcare-related laws regulating fraud and abuse, research and development, pricing, sales and marketing practices, and the privacy and security of health information, including, among others: (i) US federal regulations regarding quality and cost by the US Department of Health and Human Services ("HHS"), including CMS, as well as comparable state and non-US agencies responsible for reimbursement and regulation of healthcare goods and services, including laws and regulations related to kickbacks, false claims, self-referrals and healthcare fraud; (ii) the US federal Anti-Kickback Statute; (iii) the federal Physician Self-Referral Law; (iv) the False Claims Act ("FCA"); (v) the Physician Payments Sunshine Act; and (vi) numerous state laws regulating healthcare and insurance. Among other things, these laws and others generally (a) prohibit the provision of anything of value in exchange for the referral of patients or for the purchase, order, or recommendation of any item or service reimbursed by a federal healthcare program, including Medicare and Medicaid; (b) require that claims for payment submitted to federal healthcare programs be truthful; and (C) require the maintenance of certain government licenses and permits.

Data Privacy and Security Laws

We are subject to data privacy and security laws and regulations in numerous jurisdictions, as well as customer-imposed controls, as a result of having access to and processing confidential, personal and/or sensitive data in the course of our business. US federal and state laws protect the confidentiality of certain health-related and other personal information, in particular personally identifiable information such as medical records, and restrict the collection, use and disclosure of that protected information. At the federal level, the HHS promulgates health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which protect health information by regulating its use and disclosure. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose personally identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition to HIPAA, individual states also regulate data breach and security requirements and multiple governmental bodies assert authority over aspects of the protection of personal privacy. For example, a broad privacy law in California, the California Consumer Privacy Act ("CCPA"), came into effect in January 2020. The CCPA has some of the same features as the GDPR (discussed below) such as certain requirements for data collection, use and sharing practices and certain rights of consumers concerning the use, disclosure, and retention of their personal data. The CCPA has already prompted several other states to follow with similar laws. The EU General Data Protection Regulation that became effective in May 2018 ("GDPR") has imposed significantly stricter requirements in how we collect, transmit, process and retain personal data, including, among other things, in certain circumstances a requirement for almost immediate notice of data breaches to supervisory authorities and prompt notice to data subjects with significant fines for non-compliance. Several other countries such as China and Russia have passed, and other countries are considering passing, laws that require personal data relating to their citizens to be maintained on local servers and impose additional data transfer restrictions.

Environmental, Health and Safety Laws

We are subject to various environmental, health and safety laws and regulations both within and outside the US, such as those related to safe working conditions and laboratory practices. Like other companies in our industry, our manufacturing and research activities involve the purchase, storage, movement, use and disposal of substances regulated under environmental, health and safety laws, including those related to hazardous or potentially hazardous substances.

Other Laws and Regulations Governing Our Sales, Marketing and Shipping Activities

We are subject to the US Foreign Corrupt Practices Act (the "FCPA"), the UK Bribery Act and various other similar anti-corruption and anti-bribery laws. Among other things, these laws generally prohibit us and our intermediaries from offering, promising or making payments to foreign government entities or officials for the purpose of obtaining or retaining business. We are also subject to pertinent US and foreign laws relating to the import and export of finished goods, raw materials and supplies. We also must comply with various export control and trade embargo laws, which may require licenses or other authorizations for transactions within some countries or with some counterparties. Additionally, we are subject to laws and regulations governing government contracts, and failure to address these laws and regulations or comply with government contracts could harm our business by a reduction in revenue associated with these customers. We have agreements relating to the sale of our products to government entities and, as a result, we are subject to various statutes and regulations that apply to companies doing business with the government. We are also subject to investigation for compliance with the regulations governing government contracts. A failure to comply with these regulations could result in suspension of these contracts, criminal, civil and administrative penalties or debarment.

Intellectual Property

The healthcare industry has traditionally placed considerable importance on obtaining and maintaining patent, trade secret and trademark protection for commercially relevant technologies, devices, products and processes. We possess numerous patents, trade secrets and trademarks, and in the aggregate, our intellectual property is of material importance in the operation of our business. We, however, believe that no single patent, trade secret or trademark is material in relation to our business as a whole.

We actively 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 US and in other important markets worldwide is obtained. For example, the speed, accuracy and consistency in application of the law in a patent office within any particular jurisdiction are beyond our control and can be unpredictable. The resolution of issues such as these and their effect on our long-term success are also indeterminable. We have issued patents, both in the US and internationally, and have patent applications pending throughout the world.

It has been our policy to file for patent protection in the US 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.

We have registered or applied to register certain trademarks and service marks in the US and in foreign countries that are used in our business and in conjunction with the sale of our products. Our principal trademarks and the products they cover are discussed above in the section entitled “Products.”

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.

Human Capital and ESG Strategies

Human Capital Resources

As of December 31, 2021, we had approximately 1,600 employees worldwide, with approximately 1,400 employees in the US and approximately 200 employees outside of the US, none of whom are represented by a labor union. We have experienced no work stoppages and believe that our employee relations are good.

Workforce Health and Safety

We maintain health and safety programs conforming to best practices in the diagnostics industry. We are focused on minimizing risk and protecting our employees and communities by employing safe technologies and operating procedures, and in turn minimizing recordable incidents and improving safety across our organization.

Diversity and Inclusion

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. We strive to provide a positive work environment for all employees, consultants, contingent workers, vendors, and customers. One of the ways we accomplish this is by embracing a variety of diverse experiences and perspectives and being inclusive team players. We are dedicated to providing employees with a great place to work where they can offer their diverse talents, experiences and perspectives to innovate and create diagnostic solutions.

We are committed to maintaining an environment of equal employment opportunities for all job applicants and members of our team. We fulfill this commitment through a variety of measures, including internal and external posting of job openings, hiring, training and promoting employees without regard to race, color, religion, gender identity or expression, pregnancy, national origin, ancestry, citizenship, military or veteran status, disability, medical condition, marital or domestic partner status, sexual orientation, age, or any other considerations made unlawful by federal, state or local law. We prohibit discrimination based on a perception that anyone has any of these characteristics or is associated with a person who has or is perceived as having any of these characteristics. In addition, we look at company programs, policies, procedures and activities with diversity and inclusion in mind. In keeping with our core values, we are steadfast in taking action to ensure equal employment opportunity in accordance with all applicable federal, state and local laws.

As of December 31, 2021, 48% of our US employees identified as female and 53% of our US employees identified as having a racial and ethnic background other than white. As of December 31, 2021, our executive management team consisted of nine members, of whom 33% identified as female. In addition, as of December 31, 2021, our Board of Directors (the "Board") consisted of 10 members, of whom 30% identified as female and 20% identified as having a racial and ethnic background other than white.

Corporate Philanthropy

We listen to our internal and external stakeholders and translate their needs into innovative solutions. This stands true both in the products we offer and in our corporate philanthropy work. Our charitable giving programs operate under the Quidel Community Action Review and Endowment Squad ("QCARES") committee, which is responsible for quarterly review and approval of proposed charitable contributions. Our charitable giving programs and activities consist of the following:

- Matching gifts — We match charitable contributions by full-time, regular employees to qualifying non-profit organizations of up to $250 per employee annually.
- Volunteer incentive program — When an employee volunteers at an organization for a minimum of 20 hours in a calendar year, we donate $100 to that organization.
- General QCARES fund — We may donate up to $2,000 to an organization proposed by an employee.
- Community partnerships — As part of our commitment to expanding equitable access to healthcare, we have partnered with several major organizations to donate COVID-19 testing products to various communities across the nation to promote increased testing within communities to help prevent the spread of COVID-19.

Employee Benefits

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 and 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 benefits, tuition reimbursement and a wellness program. These benefits are designed to offer employees a menu of options so that each employee can select benefits most meaningful to their personal situation. We consider our employee benefits to be an important component of total compensation for our employees.

ESG Strategy

We advance diagnostics to improve the health and well-being of people around the globe. Through diagnostic innovation, we strive toward our vision of a world where everyone has access to high-quality, easy-to-use, and affordable tests that ultimately lead to improved patient outcomes. To us, sustainability means using our talent and hard work to do the most good.

Our ESG strategy focuses on three pillars: fostering a culture of happy people, operating responsibly, and driving equitable healthcare. We are committed to providing immediate and frequent access to highly accurate, affordable testing for our customers and maintaining the highest ethical standards for our suppliers, stockholders, collaborators, and employees.

Available Information

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 Securities and Exchange Commission (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.

Information about our Executive Officers

The names, ages and positions of all executive officers are listed below, followed by a discussion 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, 64, was named President, Chief Executive Officer and a member of the Board 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 nearly 40 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, 67, 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., 53, 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 March 2007 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, 66, 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.

Michelle A. Hodges, 62, 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., 65, 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., 49, became the Senior Vice President, Molecular Business Unit in August 2020. Prior to this position at Quidel, Dr. Ranalli 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.

Item 1A. Risk Factors

Operational and Strategic Risks

The COVID-19 global pandemic could adversely affect our business operations, strategy, financial performance and results of operations, the extent of which is uncertain and difficult to predict.

As a result of the COVID-19 pandemic and the related responses from government authorities, our business operations, strategy, financial performance and results of operations may be adversely impacted in a number of ways, including, but not limited to, the following:

- 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;
- our ability to meet increased demand for our COVID-19 testing products and the costs of expanding our manufacturing capacity to meet such demand;
- increased costs in our manufacturing, production and shipping processes;
- 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 affected and may in the future 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 user customers that could result in reductions in demand for routine, elective and other non-COVID-19 related healthcare procedures and testing;
- 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, or school closures or remote learning;
- a COVID-19 vaccination mandate or requirement that unvaccinated employees be tested frequently could result in employee attrition and difficulty securing future labor needs, including attrition of critically skilled labor, difficulty in obtaining services from impacted suppliers and increased costs;
- an increase in cyber-attacks given our increased public profile, particularly as a manufacturer of COVID-19 products;
- fluctuations in foreign currency exchange rates or interest rates resulting from market uncertainties;
- an increase in regulatory restrictions or continued market volatility, which could hinder our ability to execute strategic business activities, including acquisitions; and
- an increase in the volatility of our stock price.

In response to increased demand brought on by COVID-19, we have rapidly and significantly expanded, and are continuing to 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. 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. Similarly, the demand for our COVID-19 testing products could decrease if the COVID-19 pandemic subsides, which could result in our having unneeded excess capacity, which could in turn cause the value of those investments to be written down or written off.

The pandemic has resulted in government authorities implementing many measures to contain the spread of COVID-19, including travel bans and restrictions, quarantines, shelter-in-place and stay-at-home orders, and business and school shutdowns. Although many of these measures have been lifted or relaxed, they could be reinstituted if conditions deteriorate and could be in place for a significant period of time, which could adversely affect our operations. For example, at the outset of the pandemic, we temporarily closed our corporate offices and had personnel work remotely to the extent possible and may be required to do so again in the future. Further, our sales and marketing activities were, and may continue to be, adversely affected by the inability to conduct in-person sales activities, meetings, events and conferences, which could negatively impact the success of our sales and marketing strategies and our relationships with our customers.

The effects of COVID-19 may exacerbate our other risk factors described below. The degree to which COVID-19 impacts our business operations, strategy, financial performance and results of operations will depend on future developments, which are highly uncertain, continuously evolving and unpredictable, including, but not limited to, the duration of the COVID-19 pandemic, the severity of continual outbreak surges and variants, 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, strategy, 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 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, 2021, 2020 and 2019, sales of our COVID-19 products accounted for 75%, 70% and 0% and influenza products accounted for 4%, 8%, and 26%, 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 a waning of 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 US, the market is dominated by a small number of these distributors. Four of our US distributors, collectively accounted for approximately 49%, 68%, and 51% of our total revenue for the years ended December 31, 2021, 2020 and 2019, 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 taken up 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 reduce or terminate production of products they supply to us. Any inability of customers to pay us, or a reduction or termination of products supplied to us by suppliers, 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 US, 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 US 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 US 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, manufacturing of certain of our product lines is concentrated in one or more of our manufacturing facilities. 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 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 US 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 US 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 suppliers 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 IT 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 IT 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 may 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 from 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 IT and storage systems 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. The costs of maintaining adequate protection against such threats are significant and are expected to continue to increase in the future and may be material to our financial statements.

Interruptions to our third-party IT service providers and/or the inability of our digital solutions to interoperate with certain operating systems could impair the delivery of our cloud-based solutions and negatively impact our business.

We rely on a small number of third-party service providers to host and deliver our cloud-based solutions, such as our QVue Business mobile application, and any interruptions or delays in services from these service providers could impair the delivery of our cloud-based solutions. We do not control the hosting of these solutions, including data center facilities or our or other parties' access to the Internet. These facilities are vulnerable to damage or interruption from weather, natural disasters, fires, power loss, telecommunications failures, global pandemics and similar events. They are also subject to break-ins, computer viruses, sabotage, intentional acts of vandalism and other misconduct. The occurrence of any of these unanticipated problems could result in lengthy interruptions to our cloud-based solutions, which would have a serious adverse impact on our business.

We also depend on the interoperability of our mobile applications with popular mobile operating systems that we do not control, such as Android and iOS. Any changes in such systems that degrade the functionality of our digital solutions or give preferential treatment to competitors could adversely affect use of our solutions and negatively impact 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 17%, 13% and 33% of our total revenue for the years ended December 31, 2021, 2020 and 2019, 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 US laws and regulations that apply to our international operations, including US laws on import/export limitations, the FCPA, 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 US 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 US of our products sold into international markets at lower prices.

Our international operations are governed by the FCPA and similar anti-corruption laws outside the US. Global enforcement of anti-corruption laws has increased substantially in recent years, with more enforcement proceedings by US 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, 2021, we generated approximately $198.4 million in revenue denominated in currencies other than the US 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 US and throughout the world could impair political, trade and economic relations worldwide. Changes in policy in the US and other countries regarding international trade, including import and export regulation and international trade agreements, could negatively impact our business. US-imposed tariffs on goods imported from China and certain other countries have 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.

Natural disasters, public health crises, political crises and other catastrophic events or other events outside of our control may disrupt our facilities or the facilities of third parties on which we depend and adversely affect our results of operations.

We have significant operations in California, near major earthquake faults and exposure to wildfire, which make us susceptible to earthquake and fire risk. An earthquake, fire or other natural disaster or power shortages or outages could disrupt our operations or impair our critical systems, which could have an adverse effect on our results of operations. In addition, if any of our facilities, including our manufacturing or warehouse facilities, or the facilities of our suppliers, third-party service providers or customers is affected by natural disasters, such as earthquakes and fires, power shortages or outages, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict, or other events outside of our control, such as strikes or other labor unrest, our results of operations could be adversely affected. Moreover, these types of events could negatively impact customer spending in the impacted regions or depending on the severity, globally, which could also adversely impact our operating results.

Risks Related to Our Pending Business Combination

We are subject to a number of risks and uncertainties related to the pending Combinations, including, but not limited to, the risks discussed below in this section of the risk factors. For additional information about the pending Combinations and the additional risks and uncertainties related to the Combinations, see Topco's registration statement on Form S-4, filed with the SEC on January 31, 2022. For information about the defined terms used in this section, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments" in Part II, Item 7 of this Annual Report.

Completion of the Combinations is subject to certain conditions, some of which are outside of the parties' control, and if these conditions are not satisfied or waived, the Combinations will not be completed.

The closing of the Combinations is subject to certain conditions, including (i) our stockholders' approval of the Quidel Merger and related matters, (ii) Ortho shareholder approval of the Ortho Scheme and related matters, (iii) receipt of clearance from competition and foreign investment authorities in certain areas where the companies operate, (iv) the absence of any law, injunction, order or other judgment prohibiting the Combinations, (v) the effectiveness of the registration statement on Form S-4 for the Topco Shares, (vi) receipt of Nasdaq listing approval for the Topco Shares, (vii) subject to certain materiality exceptions, the accuracy of each of Ortho's and our representations and warranties in the BCA and performance by each of Ortho and us of the obligations under the BCA and (viii) the sanctioning of the Ortho Scheme by the High Court of Justice of England and Wales (the "Court") and the delivery of the order of the Court of sanctioning the Ortho Scheme to the Registrar of Companies in England and Wales.

The requirement to satisfy each of the foregoing conditions could delay completion of the Combinations for a significant period of time or prevent them from occurring at all. Any delay in completing the Combinations could cause Topco not to realize some or all of the benefits that we expect Topco to achieve if the Combinations are successfully completed within the expected timeframe. Further, as a condition to approving the Combinations, governmental authorities may impose conditions, terms, obligations or restrictions on the conduct of our business after the completion of the Combinations. Under the terms of the BCA, the parties are not required to proffer or negotiate, or agree or consent to, any action (including any contractual, behavioral or conduct restriction, agreement, commitment or remedy) that would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect (as defined in the BCA) on Topco. Notwithstanding the provisions of the BCA, if we were to become subject to any conditions, terms, obligations or restrictions (whether because such conditions, terms, obligations and restrictions do not rise to the specified level of materiality or because we consent to their imposition), it is possible that such conditions, terms, obligations or restrictions will delay completion of the Combinations or otherwise adversely affect our business, financial condition, or operations. Furthermore, governmental authorities may require that we divest assets or businesses as a condition to the closing of the Combinations. If we are required to divest assets or businesses, there can be no assurance that we will be able to negotiate such divestitures expeditiously or on favorable terms or that the governmental authorities will approve the terms of such divestitures. There can be no assurance that the conditions to the closing of the Combinations will be satisfied or, where applicable, waived or that the Combinations will be completed.

In addition, if Ortho has not received the necessary Court and shareholder approvals by September 22, 2022 (subject to certain extension rights), either party may choose not to proceed with the Combinations. The parties may also terminate the BCA under certain specified circumstances, including, among others, in order to enter into an agreement with respect to an all-cash proposal (A) that is determined by our Board, in the case of a proposal to us, or (B) that is determined by the Ortho board of directors, in the case of a proposal to Ortho, to be superior to the BCA, subject to the terms and conditions of the BCA (including a requirement that the terminating party pay a termination fee to the other party in accordance with the BCA).

Failure to complete the Combinations could negatively impact our stock price and future business and financial results.

If the Combinations are not completed for any reason, including as a result of our stockholders failing to adopt the BCA or Ortho shareholders failing to approve the Ortho Scheme, our ongoing business may be adversely affected and, without realizing any of the benefits of having completed the Combinations, we would be subject to a number of risks, including the following:

- we may be required, under certain circumstances, to pay Ortho a termination fee of approximately $208 million or reimburse Ortho for certain fees and expenses;
- we are subject to certain restrictions on the conduct of our business prior to completing the Combinations, which may adversely affect our ability to execute certain of our business strategies going forward if the Combinations are not completed;
- we have incurred and will continue to incur significant costs and fees associated with the proposed Combinations, such as legal, accounting, financial advisor and printing fees, regardless of whether the Combinations are completed;
- we may experience negative reactions from the financial markets, including negative impacts on our stock price;
- we may experience negative reactions from our customers, regulators and employees; and
- matters relating to the Combinations (including integration planning) will require substantial commitments of time and resources by our management, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as an independent company.

In addition, we could be subject to litigation related to any failure to complete the Combinations or related to any enforcement proceeding commenced against us to perform our obligations under the BCA. If the Combinations are not completed, these risks may materialize and may adversely affect our business, financial condition, financial results and stock price.

The BCA contains provisions that restrict our ability to pursue alternatives to the Combinations and, in specified circumstances, would require us to pay Ortho a termination fee.

Under the BCA, we are restricted, subject to certain exceptions, from soliciting, initiating, knowingly encouraging or facilitating, discussing or negotiating, or furnishing non-public information with regard to, any inquiry, proposal or offer for a competing acquisition proposal from any person or entity. If we receive a competing acquisition proposal and our Board determines (after consultation with our financial advisors and outside legal counsel) that such proposal constitutes a Quidel All Cash Superior Proposal (as defined in the BCA), and our Board makes a change in recommendation in response to such proposal to our stockholders, we would be entitled, upon complying with certain requirements, to terminate the BCA, subject to the terms of the BCA. Under such circumstances, we may be required to pay Ortho a termination fee of approximately $208 million or may be required to reimburse Ortho for its out-of-pocket expenses incurred in connection with the BCA. These provisions could discourage a third party that may have an interest in acquiring all or a significant part of us from considering or proposing such an acquisition, even if such third party was prepared to enter into a transaction that would be more favorable to us and our stockholders than the Combinations.

We will incur significant transaction and merger-related costs in connection with the Combinations.

We have incurred and expect to incur a number of non-recurring direct and indirect costs associated with the Combinations. These costs and expenses include fees paid to financial, legal and accounting advisors, severance and other potential employment-related costs, including payments that may be made to certain of our executives, filing fees, printing expenses and other related charges. Some of these costs are payable by us regardless of whether the Combinations are completed. There are also processes, policies, procedures, operations, technologies and systems that must be integrated in connection with the Combinations and the integration of the two companies' businesses. While we have assumed that a certain level of expenses would be incurred in connection with the Combinations and the other transactions contemplated by the BCA and continue to assess the magnitude of these costs, there are many factors beyond our control that could affect the total amount or the timing of the integration and implementation expenses.

There may also be additional unanticipated significant costs in connection with the Combinations that we may not recoup. These costs and expenses could reduce the realization of efficiencies and strategic benefits we expect Topco to achieve from the Combinations. Although we expect that these benefits will offset the transaction expenses and implementation costs over time, this net benefit may not be achieved in the near term or at all.

We may have difficulty attracting, motivating and retaining executives and other key employees due to uncertainty associated with the Combinations.

Topco's success after completion of the Combinations will depend in part upon the ability of Topco to retain our key employees. Competition for qualified personnel can be intense. Our current and prospective employees may experience uncertainty about the effect of the Combinations, which may impair our ability to attract, retain and motivate key management, sales, marketing, manufacturing, technical and other personnel prior to and following the Combinations. Employee retention may be particularly challenging during the pendency of the Combinations, as our employees may experience uncertainty about their future roles with Topco.

In addition, pursuant to severance provisions in our executive employment agreements, certain of our key employees are entitled to receive severance payments upon certain qualifying terminations of their employment. Certain of our key employees potentially could terminate their employment following specified circumstances set forth in the applicable executive employment agreement, including certain changes in such key employees' title, status, authority, duties, responsibilities or compensation, and be entitled to receive severance. Such circumstances could occur in connection with the Combinations as a result of changes in roles and responsibilities.

While we may employ the use of certain retention programs, there can be no guarantee that they will prove to be successful. If our key employees depart, the integration of the companies may be more difficult and Topco's business following the Combinations may be harmed. Furthermore, Topco may be required to incur significant costs in identifying, hiring, training and retaining replacements for departing employees and may lose significant expertise and talent relating to our business, which may adversely affect Topco's ability to realize the anticipated benefits of the Combinations. In addition, there could be disruptions to or distractions for the workforce and management associated with activities of labor unions or works councils or integrating employees into Topco. Accordingly, no assurance can be given that Topco will be able to attract or retain our key employees to the same extent that we have been able to attract or retain our own employees in the past.

Our business relationships may be subject to disruption due to uncertainty associated with the Combinations.

Companies with which we do business may experience uncertainty associated with the Combinations, including with respect to current or future business relationships with us or Topco. Our business relationships may be subject to disruption as customers, distributors, suppliers, vendors and others may attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than us. These disruptions could have an adverse effect on our business, financial condition, results of operations or prospects if the Combinations are not completed, or that of Topco if the Combinations are completed, including an adverse effect on Topco's ability to realize the anticipated benefits of the Combinations. The risk and adverse effect of such disruptions could be exacerbated by a delay in completion of the Combinations.

Completion of the Combinations may trigger change-in-control or other provisions in certain agreements that we are party to.

The completion of the Combinations may trigger change-in-control or other provisions in certain agreements that we are party to. If we are unable to negotiate waivers of those provisions, the respective counterparties may exercise their rights and remedies under the applicable agreements, including in some instances potentially terminating the agreements or seeking monetary damages. Even if we are able to negotiate waivers, the respective counterparties may require a fee for such waivers or seek to renegotiate the agreements on terms less favorable to the combined 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 US 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 US 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 the 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 US. 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 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;
- 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 $2.0 million, $2.4 million and $1.1 million for the years ended December 31, 2021, 2020 and 2019, 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 HHS 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 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 HHS 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 US, 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 US 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 meter-based 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.

Additionally, once a medical device is permitted to be legally marketed in the US pursuant to a 510(k) clearance, a manufacturer may be required to notify the FDA of certain modifications to the device (similar requirements apply in other jurisdictions). Manufacturers determine in the first instance whether a change to a product requires a new 510(k) clearance or premarket submission, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or other premarket submissions were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance. If the FDA disagrees with our determinations and requires us to submit new 510(k) notifications, we may be required to cease marketing or to recall the modified product until we obtain clearance, and we may be subject to civil and criminal, monetary and non-monetary penalties and damage to our reputation.

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 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 NIH 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 US government generally require us to comply with the Federal Acquisition Regulations, FCA, Procurement Integrity Act, Buy American Act and Trade Agreements Act. Government contracts subject us 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 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. If the FTC or FDA allege or establish that any of our communications are misleading, we could be subject to litigation and material penalties and fines. 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.

Complying with various US federal, state and foreign privacy and data security laws and privacy requirements from our customers could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Certain of our digital solutions, such as our QVue Business mobile application, collect, use, process, and store personal or identifying information regarding customers or other end users, and we are subject to privacy and data security laws and regulations that impose obligations in connection with the collection, use, processing and storage of such personal or identifying information. US federal, state and foreign governments and agencies in the jurisdictions in which we operate and in which our customers operate have adopted, are considering adopting or may adopt new privacy and data security laws and regulations regarding the collection, use, processing and storage of information obtained from consumers and other end users, which could impact our ability to offer certain of our digital solutions and services in certain jurisdictions. Furthermore, foreign privacy laws impose significant obligations on US 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. Privacy laws and regulations relating to the collection, use, disclosure, security and other processing of individuals' information can vary significantly from jurisdiction to jurisdiction. Uncertainty and changes in the requirements of multiple jurisdictions may increase the cost of compliance, delay or reduce demand for certain of our digital solutions, restrict our ability to offer certain digital solutions in certain jurisdictions or subject us to sanctions by US federal and state and foreign data protection regulators, all of which could negatively impact our business.

We also may be bound by contractual obligations and other obligations relating to privacy, data protection and information security that are more stringent than applicable privacy laws and regulations. The costs of compliance with, and other burdens imposed by, laws, regulations, standards and other contractual obligations relating to privacy, data protection and information security are significant. In addition, some companies, particularly larger or global enterprises, often will not contract with vendors that do not meet these rigorous standards and often seek contractual terms to ensure we are financially liable for any breach of laws or regulations.

In addition to government actions, privacy advocacy groups, the technology industry and other industries have established or may establish various new, additional or different self-regulatory standards that may place additional burdens on us. Our customers may expect us to meet voluntary certifications or adhere to other standards established by them or third parties, and we may be required or otherwise find it advisable to obtain certain of these certifications or adhere to these standards. If we are unable to maintain these certifications or meet these standards, it could reduce demand for our solutions and adversely affect our business.

Our actual or perceived failure to comply with these privacy and data security laws or privacy requirements may limit or delay the use and adoption of our digital solutions, reduce overall demand for our digital solutions or lead to regulatory investigations, breach of contract claims, litigation or significant fines, penalties or liabilities for actual or alleged noncompliance, any of which could negatively impact our business.

Changes in tax law relating to multinational corporations could adversely affect our tax position.

The US Congress, government agencies in non-US jurisdictions where we and our affiliates do business, and the Organisation for Economic Co-operation and Development ("OECD") have focused on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," for which the OECD has released several components of its comprehensive plan that have been adopted and expanded by many taxing authorities to address perceived tax abuse and inconsistencies between tax jurisdictions. As a result, the tax laws in the US and other countries in which we do business could change on a prospective or retroactive basis, and any such changes could adversely affect our business and financial statements.

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 US, as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a relatively small executive team, acquisitions, including the pending Combinations, 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, including the pending Combinations, 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.

Transitioning the BNP Business to Beckman presents certain risks to our business and operations.

On October 6, 2017, we acquired the Triage and BNP Businesses from Alere. On July 24, 2021, we entered into agreements with Beckman to transition the BNP Business to Beckman. Pursuant to these agreements, we are obligated to supply to Beckman the antibody that Beckman uses in manufacturing its BNP tests and Beckman is obligated to pay us annual payments (payable quarterly) based on the sales volume of Beckman's BNP tests, which payments are subject to agreed upon aggregate minimum and maximum amounts per year. These agreements also obligate us to pay to Alere the deferred consideration payable for the BNP Business even if Beckman does not make the guaranteed minimum payments to us, whether as a result of Beckman's failure to perform under the agreements, our failure to supply the antibody needed to manufacture the BNP tests or otherwise, which presents risks to our business and operations.

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, including to fund the cash consideration payable in connection with the Combinations. 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. In addition to our Revolving Credit Facility, we will continue to have the ability to incur additional debt. We also have 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. Additionally, as discussed under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments" in Part II, Item 7 of this Annual Report, if the Combinations are completed, Ortho's current net debt of $2.1 billion is expected to continue to be outstanding following the closing of the Combinations.

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 US and in various non-US jurisdictions. In addition, the amount of income taxes we pay is subject to ongoing audits by US federal, state and local tax authorities and by non-US 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 US or in other jurisdictions 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 common 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 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.

Expectations of our performance related to ESG matters may impose additional costs on us and expose us to new risks.

There is an increasing focus from certain investors, customers, vendors, employees and other stakeholders concerning corporate responsibility, specifically related to ESG factors. Many investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG performance is inadequate. Third-party providers of corporate responsibility ratings and reports have increased in number to meet growing investor demand for measurement of ESG performance. The criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our performance related to corporate responsibility and ESG matters is inadequate. Moreover, our market capitalization has increased significantly in the last couple of years. Accordingly, we may be benchmarked against larger peer companies, some of which may have more resources than us and thus may have achieved better ESG performance and/or a higher ESG rating profile. We may face reputational damage if our ESG performance or ESG rating profile is, or is perceived as being, below those of our competitors or peer companies. In addition, we could fail, or be perceived as failing, in our achievement of certain ESG-related initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, customers, vendors, employees and other stakeholders related to our ESG performance or our ESG initiatives are not executed as planned, it could adversely affect our reputation, business, stock price, financial condition or results of operation.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At December 31, 2021, 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	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)	Owned (2)	N/A	78,000	Administrative offices, research and development and manufacturing
San Diego, CA (High Bluff)	Leased	2022	30,000	This office facility was vacated in 2019 and sublet to a third party in 2020
Athens, OH	Leased	2027	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 to the Consolidated Financial Statements included in this Annual Report.

(2) A wholly owned subsidiary of the Company purchased the McKellar property in August 2021. Prior to the purchase date, the Company was leasing the property through 2030.

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 to 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 11, 2022, we had approximately 268 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, 2021:

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)
October 4, 2021 - October 31, 2021	5,281	$ 130.16	—	$ 52,894,442
November 1, 2021 - November 28, 2021	2,914	140.72	—	52,894,442
November 29, 2021 - January 2, 2022	274	139.79	—	52,894,442
Total	8,469	$ 134.11	—	$ 52,894,442

(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 option exercise transactions and equity award vesting.

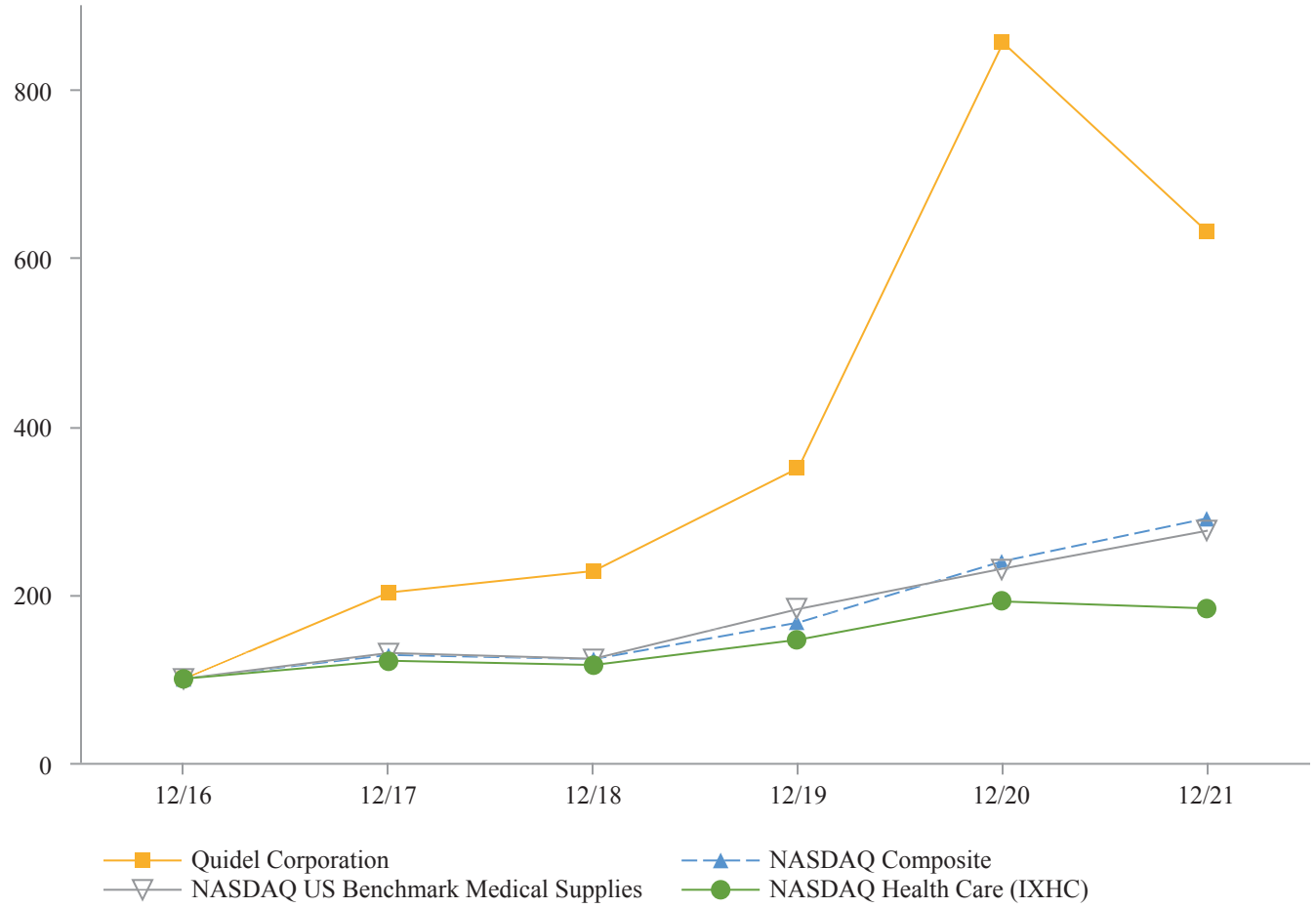
(2) On December 18, 2018, the Company announced a stock repurchase program to repurchase up to $50.0 million of the Company's common stock, which was authorized by the Board on December 12, 2018. On August 28, 2020, the Board authorized an increase of an additional $150.0 million to the Company's existing stock repurchase program authorization, which was announced on September 1, 2020. The Board also extended the stock repurchase program 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 US Benchmark Medical Supplies Index and Nasdaq Health Care Index for the period beginning December 31, 2016 and ending December 31, 2021. The graph assumes (i) an initial investment of $100 on December 31, 2016 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 and the Nasdaq Composite, Nasdaq US Benchmark Medical Supplies and Nasdaq Health Care Indices



Company/Index	Base Period 12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Quidel Corporation	**$ 100.00**	$ 202.38	$ 227.92	$ 350.28	$ 855.46	$ 630.21
Nasdaq Composite	**$ 100.00**	$ 128.24	$ 123.26	$ 166.68	$ 239.63	$ 290.63
Nasdaq US Benchmark Medical Supplies	**$ 100.00**	$ 130.54	$ 123.68	$ 182.74	$ 230.76	$ 275.85
Nasdaq Health Care	**$ 100.00**	$ 121.30	$ 116.25	$ 146.27	$ 191.72	$ 183.47

Item 6. [Reserved]

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 the "Risk Factors" starting on page 22 of 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. Discussion of our 2019 fiscal year specifically, as well as the year-to-year comparisons of our 2020 financial performance to 2019, that are not included in this Annual Report can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report for the year ended December 31, 2020.

Overview and Executive Summary

Our primary mission is to advance diagnostics to improve human health. We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. We separate these 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, as well as for individual, non-professional, OTC use. More recently, we have begun to reach significant new markets as we introduced our QuickVue At-Home OTC COVID-19 test for reopening schools, and for health departments, employers, entertainment centers and many other locations. We market our products through a network of distributors and a direct sales force. We operate in one business segment that develops, manufactures and markets our products globally.

For the year ended December 31, 2021, total revenue increased 2% to $1,698.6 million as compared to the year ended December 31, 2020, 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 years ended December 31, 2021 and 2020, sales of our COVID-19 products accounted for 75% and 70% of total revenue, respectively. For the years ended December 31, 2021, 2020 and 2019, sales of our influenza products, as a percentage of total revenue, accounted for 4%, 8%, and 26%, respectively. Additionally, a significant portion of our total revenue is from a relatively small number of distributors. Approximately 49%, 68% and 51% of our total revenue for the years ended December 31, 2021, 2020 and 2019, respectively, were related to sales through our four largest distributors.

Recent Developments

On December 22, 2021, we entered into the BCA with Ortho, Topco, US Holdco Sub, US Merger Sub and US Holdco Sub 2. Under the terms of the BCA, we are entering into the Combinations with Ortho under Topco, a new holding company. The Combinations are expected to be implemented by way of (i) a scheme of arrangement to be undertaken by Ortho under Part 26 of the UK Companies Act 2006 (the "Ortho Scheme"), pursuant to which each issued and outstanding share of Ortho (the "Ortho Shares") will be acquired by a nominee of Topco, such that Ortho will become a wholly owned subsidiary of Topco, and (ii) a merger (the "Quidel Merger") of US Merger Sub with and into us immediately following consummation of the Ortho Scheme, with us surviving the merger as a wholly owned subsidiary of Topco.

At the effective time of the Ortho Scheme, each Ortho Share will be acquired by a nominee on behalf and for the benefit of Topco in exchange for 0.1055 shares of common stock of Topco (the "Topco Shares") and $7.14 in cash. At the effective time of the Quidel Merger, each share of our common stock (each, a "Quidel Share") will be converted into the right to receive one Topco Share. Ortho will be acquired for total consideration of approximately $4.3 billion (which is based on the February 9, 2022 closing price of $97.64 per Quidel Share), including $1.75 billion of cash, funded through cash on our balance sheet and expected incremental borrowings. Following the closing of the Combinations, Ortho's current net debt of $2.1 billion is expected to continue to be outstanding.

If the Combinations are completed, Ortho shareholders are expected to own approximately 38% of Topco on a fully diluted basis and our stockholders are expected to own approximately 62% of Topco on a fully diluted basis, based on Ortho's capitalization and our capitalization as of the date of the BCA. The parties intend to list the Topco Shares to be issued in the Combinations on Nasdaq. For additional information about the pending Combinations and the preliminary unaudited pro forma financial information, see Topco's registration statement on Form S-4, filed with the SEC on January 31, 2022.

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 of global dissemination and effectiveness of the vaccination and containment efforts throughout the world, the duration and spread of the virus, as well as seasonality, variants or new outbreaks.

In the US, federal, state, and local government directives and policies have been put in place to manage public health concerns and address the economic impacts, including reduced business activity and overall uncertainty presented by this new healthcare challenge. Similar actions have been taken by governments around the world. While all our facilities 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 extent to which COVID-19 may impact 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 POC diagnostics and with established expertise in respiratory infectious disease products, we were and remain well-positioned to respond to the COVID-19 pandemic. We work 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 developed new molecular and antigen products to diagnose the SARS-CoV-2 virus. We have experienced exceptional demand for such products. In response, we committed 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, especially in the US. At the same time, we also have observed fluctuating demand for certain of our other diagnostic products. 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 COVID-19, regulatory changes in any of the markets in which we serve, impact of new SARS-CoV-2 variants and actions to contain and treat their impact, including the vaccination programs that have been implemented.

Operations and Employee Safety

While many governments implemented lockdown and shelter-in-place orders, requiring non-essential businesses to shut down operations, our business is deemed “essential” and we continued to operate, manufacture and distribute products to customers. We 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 implemented preventative protocols intended to help safeguard our on-site employees and maintain business continuity. These measures have created additional burdens on our infrastructure and IT 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 receiving certain raw materials and components for our products. Such delays can result in disruption to our business operations. In response, we have increased safety stock of certain critical components and finished goods, for which we have seen extraordinary demand. We are continuously evaluating our supply chain to identify potential gaps and take steps intended to help 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 may fluctuate due to supply chain variability 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 began operations in October 2021.

We are seeking to minimize the impact of delays and secure allocations of vital raw materials to meet demand for our products. However, dependent on the mitigation efforts, we may continue to experience 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

Our financial performance and results of operations will depend on future developments and other factors that are highly uncertain, continuously evolving and unpredictable, including the duration, severity and continuation of outbreak surges of the COVID-19 pandemic and actions to contain the spread of the virus such as mask wearing, social distancing and vaccination efforts globally. While demand for COVID-19 testing can fluctuate dramatically, as we have seen in 2021, we believe some level of COVID-19 testing demand will be sustainable through at least 2022. We believe ongoing COVID-19 testing will be required as communities attempt a return to more normal practices in schools, the workplace and entertainment venues. With respect to our core products, we anticipate revenue growth, assuming a normalized respiratory season.

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. Additionally, we are making substantial investments in the expansion of our production capacity. While initially this expansion was to address the testing demand driven by the COVID-19 pandemic, in the long-term, we expect this expansion to provide increased flexibility to address opportunities for new products and new markets globally. 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 strategic opportunities to acquire new product lines, technologies and companies.

Results of Operations

Comparison of years ended December 31, 2021 and 2020

Our fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. Fiscal year 2021 was 52 weeks and fiscal year 2020 was 53 weeks.

Total Revenues

The following table compares total revenues for the years ended December 31, 2021 and 2020 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2021	2020	$	%
Rapid Immunoassay	$ 1,197,459	$ 1,144,831	$ 52,628	5 %
Cardiometabolic Immunoassay	255,788	242,933	12,855	5 %
Molecular Diagnostic Solutions	200,487	222,964	(22,477)	(10)%
Specialized Diagnostic Solutions	44,817	50,940	(6,123)	(12)%
Total revenues	$ 1,698,551	$ 1,661,668	$ 36,883	2 %

For the year ended December 31, 2021, total revenues increased 2% to $1,698.6 million. The Rapid Immunoassay category was the largest contributor to revenue growth, driven by sales of the QuickVue SARS Antigen assay. Cardiometabolic Immunoassay sales increased $12.9 million over the prior year as COVID-19 restrictions began to be lifted and sales of our Triage products approached pre-pandemic levels. Growth in our Triage Business was partially offset by lower revenues recognized for the Beckman BNP products due to the transition of this business to Beckman in August 2021. The decline in Molecular Diagnostic Solutions sales over the prior year was driven primarily by decreased pricing for the Lyra SARS Antigen assay, partially offset by higher sales of the Solana SARS Antigen assay. The decrease in Specialized Diagnostic Solutions sales over the prior year was driven by lower sales of our cell culture products, primarily due to the lack of a respiratory season in early 2021. Currency exchange rate impact for the year ended December 31, 2021 was favorable by $7.9 million, which had a minimal impact on the growth rate. See Item 7A of this Annual Report for additional information related to our calculation and use of constant currency revenue and the constant currency fluctuation rate.

Gross Profit

Gross profit for the year ended December 31, 2021 was $1,270.9 million, or 75% of revenue, compared to $1,348.9 million, or 81% of revenue for the year ended December 31, 2020. The decreased gross profit was driven by a shift in product mix from Sofia SARS products to QuickVue SARS products and lower selling prices for our SARS products in 2021. Increases in supply chain and other indirect manufacturing costs were more than offset by increased absorption driven by higher production volumes. Gross margin declined compared to the prior year due to the same factors.

Operating Expenses

The following table compares operating expenses for the years ended December 31, 2021 and 2020 (in thousands, except percentages):

	For the year ended December 31,					
	2021		2020		Increase (decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$ 95,701	6 %	$ 84,292	5 %	$ 11,409	14 %
Sales and marketing	$ 175,325	10 %	$ 133,957	8 %	$ 41,368	31 %
General and administrative	$ 84,247	5 %	$ 66,586	4 %	$ 17,661	27 %
Acquisition and integration costs	$ 9,557	1 %	$ 3,694	— %	$ 5,863	159 %

Research and Development Expense

Research and development expense for the year ended December 31, 2021 increased to $95.7 million from $84.3 million for the prior year primarily due to increased spending on Savanna and QuickVue OTC projects, partially offset by decreased spending on Sofia projects. We incurred higher labor, material and clinical trials spending associated with COVID-19 product development.

Research and development expenses include direct external costs such as fees paid to third-party contractors and 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, software licenses, 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, 2021 increased to $175.3 million from $134.0 million for the prior year due to increased freight expense from greater shipment volumes, higher promotional spending associated with the launch of the QuickVue At-Home OTC COVID-19 test, higher labor costs and increased travel and meeting costs as COVID-19 related travel restrictions eased, partially offset by reduced bad debt expense.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2021 increased to $84.2 million from $66.6 million for the prior year due to higher compensation costs from increased headcount to support the growth of the business experienced in 2021, and higher charitable contributions and stock compensation expense.

Acquisition and Integration Costs

Acquisition and integration costs of $9.6 million and $3.7 million for the years ended December 31, 2021 and 2020, respectively, primarily related to the evaluation of new business development opportunities, including the pending Combinations in the year ended December 31, 2021.

Other Expense, Net

The following table compares Other expense, net, for the years ended December 31, 2021 and 2020 (in thousands, except percentages):

	For the year ended December 31,		Increase (decrease)	
	2021	2020	$	%
Interest and other expense, net	$ 5,706	$ 9,623	$ (3,917)	(41)%
Loss on extinguishment of debt	—	10,384	(10,384)	(100)%
Total other expense, net	$ 5,706	$ 20,007	$ (14,301)	(71)%

Interest and other expense, net primarily relates to accretion of interest on the deferred consideration, coupon and accretion of interest related to our 3.25% Convertible Senior Notes due 2020 ("Convertible Notes") (in the 2020 period) and interest and amortization of deferred financing costs associated with our Credit Agreement (as defined herein). Interest and other expense, net for the year ended December 31, 2021 decreased to $5.7 million from $9.6 million for the prior year. The decrease in interest and other expense, net over the prior year was primarily due to the maturity of our Convertible Notes in December 2020, which included an unfavorable $1.1 million change in fair value of derivative liabilities associated with a Convertible Notes conversion in the second quarter of 2020. Additionally, interest expense decreased due to lower deferred consideration liability outstanding during 2021.

Loss on extinguishment of debt of $10.4 million for the year ended December 31, 2020 related to the extinguishment of $5.9 million in aggregate principal amount of the Convertible Notes, which were converted and settled in cash during the period.

Income Taxes

We recognized an income tax provision of $196.1 million, resulting in an effective tax rate of 21.8% for the year ended December 31, 2021. This effective tax rate is comparable to the effective tax rate of 22.1% for the year ended December 31, 2020. In both years, the effective tax rate differs from the federal statutory rate of 21% due to increases from the state tax provision, slightly offset by tax benefits from the foreign-derived intangible income deduction, excess stock-based compensation deductions and federal and state research credits.

Liquidity and Capital Resources

As of December 31, 2021 and 2020, our principal sources of liquidity consisted of the following (in thousands):

	December 31,	
	2021	2020
Cash and cash equivalents	$ 802,751	$ 489,941
Marketable securities, current	25,758	—
Marketable securities, non-current	37,852	—
Total cash, cash equivalents and marketable securities	$ 866,361	$ 489,941
Amount available to borrow under the Revolving Credit Facility	$ 175,000	$ 175,000
Working capital including cash and cash equivalents and marketable securities, current	$ 1,116,790	$ 805,441

As of December 31, 2021, we had $802.8 million in cash and cash equivalents, a $312.8 million increase from the prior year driven primarily by cash generated from operations. Additionally, during the year ended December 31, 2021, we invested a portion of our excess cash balances in a portfolio of investment-grade corporate debt securities and asset-backed securities. Our cash requirements fluctuate as a result of numerous factors, such as cash generated from operations, progress in research and development, capital expansion projects and acquisition and business development activities. We also intend to continue to evaluate candidates for new product lines, company or technology acquisitions, technology licensing or 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. On December 22, 2021, we entered into the BCA, pursuant to which we will be entering into a business combination with Ortho under Topco, a new holding company. Ortho will be acquired for total consideration of approximately $4.3 billion (which is based on the February 9, 2022 closing price of $97.64 per Quidel Share), including $1.75 billion of cash, funded through cash on our balance sheet and expected incremental borrowings. Following the closing of the Combinations, Ortho's current net debt of $2.1 billion is expected to continue to be outstanding.

Our primary source of liquidity, other than our holdings of cash and cash equivalents, has been cash flows from operations. 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 and incremental borrowings 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, research and development, 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 Notes matured on December 15, 2020. The Amended and Restated Credit Agreement (the "Credit Agreement") provides us with a Revolving Credit Facility of $175.0 million and there was no balance outstanding as of December 31, 2021 or 2020. The Revolving Credit Facility matures on August 31, 2023.

As of December 31, 2021, we have $6.1 million in fair value of contingent consideration and $78.4 million of deferred consideration associated with acquisitions to be settled in future periods.

On December 12, 2018, the Board authorized a stock repurchase program, allowing the Company to repurchase up to $50.0 million of its common stock. On August 28, 2020, the Board approved an amendment to the stock repurchase program that authorized repurchases of an additional $150.0 million of our common stock through August 28, 2022. For the twelve months ended December 31, 2021, 957,239 shares of outstanding common stock were repurchased under our stock repurchase program for approximately $103.4 million and as of December 31, 2021, we had approximately $52.9 million available under the stock 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

(in thousands)	Year ended December 31, 2021	2020
Net cash provided by operating activities	$ 805,869	$ 629,763
Net cash used for investing activities	(319,530)	(63,322)
Net cash used for financing activities	(173,177)	(130,277)
Effect of exchange rate changes on cash	(352)	1,002
Net increase in cash and cash equivalents	$ 312,810	$ 437,166

Cash provided by operating activities of $805.9 million during the twelve months ended December 31, 2021 reflects net income of $704.2 million and non-cash adjustments of $104.4 million primarily associated with depreciation, amortization, stock-based compensation, deferred taxes, and accretion of interest on deferred consideration. Partially offsetting these inflows was a net working capital use of cash of $30.7 million primarily driven by an increase in product inventory associated with the increased demand due to the COVID-19 pandemic and a decrease in income taxes payable, partially offset by a decrease in accounts receivable.

Cash provided by operating activities of $629.8 million during the year ended December 31, 2020 reflects net income of $810.3 million and non-cash 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, partially offset by increases in income taxes payable and accounts payable.

Our investing activities used $319.5 million during the twelve months ended December 31, 2021 primarily related to investments in manufacturing equipment and building improvements, Sofia, Solana and Triage instruments available for lease and purchases of scientific equipment, partially offset by government proceeds received to fund such investments. Additionally, we purchased $67.4 million of available-for-sale securities and sold $3.8 million of our available-for-sale securities during 2021. Our investing activities used $63.3 million during the year ended December 31, 2020 primarily related to investments in manufacturing equipment, Sofia, Solana and Triage instruments available for lease, building improvements and purchases of scientific equipment.

We are currently planning approximately $150 million in capital expenditures over the next 12 months. The primary purposes for our capital expenditures are to invest in manufacturing capacity expansion, acquire Savanna, Sofia, Solana and Triage instruments, acquire scientific equipment, purchase or develop IT systems and implement facility improvements. We have $3.4 million in firm purchase commitments with respect to planned inventory purchases as of December 31, 2021. We plan to fund the capital expenditures with the cash on our balance sheet.

Cash used by financing activities was $173.2 million during the twelve months ended December 31, 2021 primarily related to repurchases of common stock of $103.4 million, payments on deferred consideration of $35.1 million, and acquisition contingent consideration of $4.7 million, partially offset by proceeds of $7.6 million from the issuance of common stock under our Amended and Restated 1983 Employee Stock Purchase Plan (the “ESPP”) and pursuant to stock option exercises . Cash used by financing activities was $130.3 million during the year ended December 31, 2020 primarily related to repurchases of common stock of $43.7 million, payment on Convertible 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 of $9.6 million from the issuance of common stock under the ESPP and pursuant to stock option exercises.

Contractual Obligations

As of December 31, 2021, 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 and contingent consideration (1)	$ 88,000	$ 48,000	$ 40,000	$ —	$ —
Finance lease obligation (2)	668	272	396	—	—
Operating lease obligations (3)	195,264	15,468	31,168	31,793	116,835
Non-cancelable purchase commitment (4)	3,400	1,263	546	446	1,145
Total contractual obligations	$ 287,332	$ 65,003	$ 72,110	$ 32,239	$ 117,980

(1) Reflects the deferred and contingent consideration payments related to the acquisition of the BNP Business.
(2) Finance lease obligations include payments through 2024.
(3) Reflects future minimum lease obligations on facilities and equipment under operating leases in place as of December 31, 2021. 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.
(4) Reflects our $3.4 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 $2.0 million, $2.4 million and $1.1 million for the years ended December 31, 2021, 2020 and 2019, 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, 2021, we had approximately $11.6 million of liabilities associated with uncertain tax positions. See Note 4 to the Consolidated Financial Statements included in this Annual Report for further discussion of uncertain tax positions.

Critical Accounting 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 US ("GAAP"). 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

We record 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. The allowance for contractual rebates involves estimating adjustments to revenue based upon a high volume of data including inputs from third-party sources. 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. At December 31, 2021, the reserve related to contract rebates was $40.3 million, a decrease of $60.5 million from the prior year.

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, 2021 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, 2021, we had a valuation allowance of $2.3 million, which represents the portion of our 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 to 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

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 investments, our cash equivalents as of December 31, 2021 consisted primarily of prime money market funds. These funds provide daily liquidity and may be subject to interest rate risk and decrease 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 balances with foreign subsidiaries and transactions denominated in currencies other than the functional currency of the local jurisdiction.

For the year ended December 31, 2021, total revenues were $1,698.6 million, of which approximately $198.4 million were denominated in currencies other than the US dollar. We believe constant currency revenue and the related constant currency fluctuation rate, which are non-GAAP measures, enhance the comparison of our financial results from period-to-period and to that of our competitors because they present our operating performance without the effect of exchange rate variances. Constant currency revenue excludes the impact from foreign currency fluctuations, which was favorable by $7.9 million for the year ended December 31, 2021, and is calculated by (i) translating current period revenues using prior period exchange rates and (ii) excluding any hedging effect recognized in the current period. The constant currency fluctuation rate (expressed as a percentage) is calculated by determining the change in current period constant currency revenue compared to prior period revenue.

The major currencies to which our revenues are exposed are the Euro, the Chinese Yuan and the Canadian dollar. 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, 2021 as follows (in thousands):

Currency	Year ended December 31, 2021	
Chinese Yuan	$	4,420
Euro	$	4,272
Canadian Dollar	$	6,862

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 Note 12 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 17, 2022 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, 2021, the Company recognized an allowance on accounts receivable of $40.3 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 17, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 802,751	$ 489,941
Marketable securities	25,758	—
Accounts receivable, net	377,969	497,688
Inventories	198,765	113,798
Prepaid expenses and other current assets	35,067	40,975
Total current assets	1,440,310	1,142,402
Property, plant and equipment, net	349,202	110,481
Marketable securities, non-current	37,852	—
Right-of-use assets	127,622	100,544
Goodwill	337,021	337,032
Intangible assets, net	98,655	122,431
Deferred tax asset	20,089	44,762
Other non-current assets	19,623	13,512
Total assets	$ 2,430,374	$ 1,871,164
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 101,492	$ 86,316
Accrued payroll and related expenses	40,385	34,781
Income taxes payable	66,945	127,788
Operating lease liabilities	10,039	7,799
Contingent consideration	5,986	5,987
Deferred consideration	41,945	42,000
Other current liabilities	56,728	32,290
Total current liabilities	323,520	336,961
Operating lease liabilities - non-current	128,556	100,706
Deferred consideration - non-current	36,491	73,951
Contingent consideration - non-current	87	5,909
Other non-current liabilities	12,358	20,934
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, 2021 and 2020	—	—
Common stock, $.001 par value per share; 97,500 shares authorized; 41,686 and 42,290 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	42	42
Additional paid-in capital	279,768	388,121
Accumulated other comprehensive income (loss)	355	(431)
Retained earnings	1,649,197	944,971
Total stockholders' equity	1,929,362	1,332,703
Total liabilities and stockholders' equity	$ 2,430,374	$ 1,871,164

See accompanying notes.

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

	Year ended December 31,		
	2021	2020	2019
Total revenues	$ 1,698,551	$ 1,661,668	$ 534,890
Cost of sales	427,656	312,813	214,085
Gross profit	1,270,895	1,348,855	320,805
Research and development	95,701	84,292	52,553
Sales and marketing	175,325	133,957	111,114
General and administrative	84,247	66,586	52,755
Acquisition and integration costs	9,557	3,694	11,667
Total operating expenses	364,830	288,529	228,089
Operating income	906,065	1,060,326	92,716
Other expense, net			
Interest and other expense, net	(5,706)	(9,623)	(14,790)
Loss on extinguishment of debt	—	(10,384)	(748)
Total other expense, net	(5,706)	(20,007)	(15,538)
Income before income taxes	900,359	1,040,319	77,178
Provision for income taxes	196,133	230,032	4,257
Net income	$ 704,226	$ 810,287	$ 72,921
Basic earnings per share	$ 16.74	$ 19.24	$ 1.78
Diluted earnings per share	$ 16.43	$ 18.60	$ 1.73
Shares used in basic per share calculation	42,078	42,124	40,860
Shares used in diluted per share calculation	42,874	43,591	43,111

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year ended December 31,		
	2021	2020	2019
Net income	$ 704,226	$ 810,287	$ 72,921
Changes in cumulative translation adjustment, net of tax	(1,588)	2,554	(322)
Changes in unrealized losses from investments, net of tax	(144)	—	—
Changes in unrealized gains (losses) from cash flow hedges:			
Net unrealized gains (losses) on derivative instruments	98	(2,993)	716
Reclassification of net realized losses (gains) on derivative instruments included in net income	2,420	471	(718)
Total change in unrealized gains (losses) from cash flow hedges, net of tax	2,518	(2,522)	(2)
Comprehensive income	$ 705,012	$ 810,319	$ 72,597

See accompanying notes.

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

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
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 Notes	1,497	1	86,427	—	—	86,428
Tax impact from the conversion of Convertible Notes	—	—	568	—	—	568
Reduction for equity component of Convertible Notes exchanged	—	—	(43,516)	—	—	(43,516)
Tax withholdings related to vesting of stock-based awards	(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 Notes	226	—	7,230	—	—	7,230
Tax impact from the conversion of Convertible Notes	—	—	54	—	—	54
Derivative liabilities - Convertible Notes elected to settle in cash	—	—	(26,180)	—	—	(26,180)
Tax withholdings related to vesting of stock-based awards	(37)		(4,198)			(4,198)
Repurchases of common stock	(257)	—	(43,691)	—	—	(43,691)
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
Issuance of common stock under equity compensation plans	534	1	9,551	—	—	9,552
Stock-based compensation expense	—	—	22,679	—	—	22,679
Tax withholdings related to vesting of stock-based awards	(181)	—	(37,146)	—	—	(37,146)
Repurchases of common stock	(957)	(1)	(103,437)	—	—	(103,438)
Other comprehensive income, net of tax	—	—	—	786	—	786
Net income	—	—	—	—	704,226	704,226
Balance at December 31, 2021	41,686	$ 42	$ 279,768	$ 355	$ 1,649,197	$ 1,929,362

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2021	**2020**	**2019**
OPERATING ACTIVITIES			
Net income	$ 704,226	$ 810,287	$ 72,921
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation, amortization and other	54,384	49,089	47,827
Stock-based compensation expense	25,406	21,019	13,252
Impairment loss	—	—	1,481
Amortization of debt discount and deferred issuance costs	403	771	1,582
Change in fair value of acquisition contingencies	217	1,405	1,467
Accretion of interest on deferred consideration	4,485	6,569	8,224
Net change in operating lease right-of-use assets and liabilities	3,012	434	3,964
Change in deferred tax assets and liabilities	24,673	(20,211)	(1,742)
Change in fair value of derivative liabilities - Convertible Notes	—	1,084	—
Payment of accreted interest on contingent and deferred consideration	(8,157)	—	—
Loss on extinguishment of debt	—	10,384	748
Changes in assets and liabilities:			
Accounts receivable	118,852	(402,094)	(36,059)
Inventories	(85,039)	(54,903)	9,143
Prepaid expenses and other current and non-current assets	(13,256)	(14,264)	4,314
Accounts payable	10,446	52,226	2,434
Accrued payroll and related expenses	4,971	16,024	(1,037)
Income taxes payable	(66,688)	137,708	4,175
Other current and non-current liabilities	27,934	14,235	1,791
Net cash provided by operating activities	805,869	629,763	134,485
INVESTING ACTIVITIES			
Acquisitions of property, equipment, investments and intangibles	(292,724)	(64,927)	(27,229)
Proceeds from government assistance allocated to fixed assets	36,881	1,605	—
Purchases of marketable securities	(67,448)	—	—
Proceeds from sale of marketable securities	3,761	—	—
Net cash used for investing activities	(319,530)	(63,322)	(27,229)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	7,550	9,613	14,782
Payments on finance lease obligation	(260)	(511)	(371)
Payments of tax withholdings related to vesting of stock-based awards	(37,146)	(4,198)	(10,728)
Payments on Revolving Credit Facility	—	—	(53,188)
Repurchases of common stock	(103,438)	(43,691)	—
Payments on acquisition contingent consideration	(4,740)	(6,044)	(4,044)
Payments of deferred consideration	(35,143)	(42,000)	(44,000)
Payment on Convertible Note and Derivative Liability	—	(43,446)	—
Transaction costs related to debt exchange	—	—	(733)
Net cash used for financing activities	(173,177)	(130,277)	(98,282)
Effect of exchange rate changes on cash	(352)	1,002	106
Net increase in cash and cash equivalents	312,810	437,166	9,080
Cash and cash equivalents, beginning of period	489,941	52,775	43,695
Cash and cash equivalents, at end of period	$ 802,751	$ 489,941	$ 52,775

	Year ended December 31,		
	2021	2020	2019
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$ —	$ 480	$ 2,295
Cash paid during the period for income taxes	$ 235,551	$ 109,912	$ 2,189
Purchase of property, equipment and intangibles by incurring current liabilities	$ 10,456	$ 7,160	$ 1,040
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	$ 2,001	$ 767	$ 2,018
Extinguishment of Convertible Notes through issuance of stock	$ —	$ 7,230	$ 86,428

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 that develops, manufactures and markets diagnostic testing solutions. These diagnostic tests are categorized into four product categories: rapid immunoassay, cardiometabolic immunoassay, molecular diagnostic solutions and specialized diagnostic solutions. The Company currently sells its 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, as well as for individual, non-professional, OTC use. 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 GAAP.

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. Cash equivalents include money market funds and debt securities of high quality institutions.

Marketable Securities—The Company invests excess cash balances in investment-grade corporate debt securities, asset-backed securities and US Treasury securities. The Company seeks to diversify investments and limits the amount of investment concentrations for individual institutions, maturities and investment types. These marketable securities are classified as available-for-sale and, accordingly, such securities are recorded at fair value. Unrealized gains and losses that are deemed temporary are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. If any adjustment to fair value reflects a significant decline in the value of the security, the Company evaluates the extent to which the decline is determined to be other-than-temporary and would mark the security to market through a charge to its Consolidated Statements of Income. Marketable securities are classified as non-current when maturities are one year or more.

Accounts Receivable—The Company sells its products directly to hospitals, reference laboratories, retail clinics, pharmacies, as well as to distributors in the US 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 $52.4 million and $103.4 million at December 31, 2021 and 2020, respectively, of which the reserve related to contract rebates was $40.3 million and $100.8 million, respectively.

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

Credit losses are identified when cash flows received are not expected to be sufficient to recover the amortized cost basis of a security. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results, with the amount of loss relating to other factors recorded in accumulated other comprehensive income (loss).

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 are 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 the Company's 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 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.

Transaction price for a contract represents the amount to which we are entitled in exchange for providing goods and services to the customer. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. 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.

During 2021, the Company generated a portion of its revenue from sales of the QuickVue At-Home OTC COVID-19 tests to retail customers. The Company estimates the transaction price for revenue from sales to retail customers based on historical experience and current trends to evaluate when uncertainties related to right of return provisions are resolved. As of December 31, 2021, due to a lack of history on which to base an estimate of products to be returned from the retailers, the Company established a reserve based upon an estimate of total inventory remaining at our retailers which was subject to return.

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 was not material in the years ended December 31, 2021, 2020 and 2019.

Government Assistance— During the year ended December 31, 2020, the Company entered into a contract with the 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 originally provided for consideration to the Company of up to $65.0 million and had a performance period of one year, which began in July 2020. During 2021, the Company entered into several amendments to the contract, which added additional deliverables and milestones, as well as extended the performance period. The contract and amendments include key deliverables and milestones that directly support the upgrade and addition of new manufacturing lines, as well as the outfitting of the 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 is 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. Amounts billed but not collected as of December 31, 2020 were included in other receivables within prepaid expenses and other current assets. As of December 31, 2021, the Company had achieved and collected payments for all milestones under the NIH contract.

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 $29.3 million, $14.2 million and $9.5 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Advertising Costs—Advertising costs are expensed as incurred. Advertising costs were $13.7 million, $1.1 million and $1.3 million for the years ended December 31, 2021, 2020 and 2019, 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 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 units 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.

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 is 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 ROU assets, operating lease liabilities and operating lease liabilities non-current in the Consolidated Balance Sheets. Finance leases are included in property, plant and equipment, net, other current liabilities and other non-current liabilities.

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

Use of Estimates—The preparation of financial statements in conformity with GAAP 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 ends on the Sunday closest to the end of the calendar quarter. The Company's fiscal year ended January 2, 2022 was 52 weeks and the Company's fiscal years ended January 3, 2021 and December 29, 2019 were 53 and 52 weeks, respectively. For ease of reference, the calendar year end dates are used herein.

Note 2. Balance Sheet Account Details

Marketable securities

The following is a summary of marketable securities (in thousands):

	December 31, 2021		
	Amortized Cost	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 22,344	$ (28)	$ 22,316
Asset-backed securities	3,443	(1)	3,442
Total marketable securities, current	25,787	(29)	25,758
Corporate bonds, non-current	26,761	(83)	26,678
Asset-backed securities, non-current	11,197	(23)	11,174
Total marketable securities	$ 63,745	$ (135)	$ 63,610

Prepaid expenses and other current assets

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

	December 31,	
	2021	2020
Unbilled receivables	$ —	$ 16,041
Other receivables	15,879	15,442
Prepaid expenses	14,598	7,335
Other	4,590	2,157
Total prepaid expenses and other current assets	$ 35,067	$ 40,975

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,	
	2021	2020
Raw materials	$ 103,159	$ 58,264
Work-in-process (materials, labor and overhead)	36,091	31,359
Finished goods (materials, labor and overhead)	59,515	24,175
Total inventories	$ 198,765	$ 113,798

Property, Plant and Equipment, net

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

	December 31,	
	2021	2020
Equipment, furniture and fixtures	$ 159,008	$ 91,838
Building and improvements	146,784	49,014
Leased instruments	68,062	60,722
Land	10,179	1,080
Construction in Progress	105,247	32,595
Total property, plant and equipment, gross	489,280	235,249
Less: accumulated depreciation and amortization	(140,078)	(124,768)
Total property, plant and equipment, net	$ 349,202	$ 110,481

Construction in progress reflects amounts incurred for construction or improvements of property, plant, or equipment that have not been made in service. In addition, 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 $24.3 million, $20.8 million and $19.4 million for the years ended December 31, 2021, 2020 and 2019, 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, 2021, which remains consistent with December 31, 2020. Finite-lived intangible assets consisted of the following (dollar amounts in thousands):

		December 31, 2021			December 31, 2020		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	9.1	$ 112,725	$ (78,204)	$ 34,521	$ 112,100	$ (71,426)	$ 40,674
Customer relationships	7.0	122,690	(77,281)	45,409	122,584	(60,688)	61,896
License agreements	9.9	6,511	(5,658)	853	6,518	(5,312)	1,206
Patent and trademark costs	10.8	28,740	(15,736)	13,004	28,740	(13,038)	15,702
Software development costs	4.6	11,705	(6,837)	4,868	8,743	(5,790)	2,953
Total finite-lived intangible assets		$ 282,371	$ (183,716)	$ 98,655	$ 278,685	$ (156,254)	$ 122,431

Amortization expense related to the capitalized software costs was $1.0 million, $0.9 million and $0.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. Amortization expense (including capitalized software costs) was $27.4 million, $27.3 million and $27.5 million for the years ended December 31, 2021, 2020 and 2019, respectively.

The expected future annual amortization expense of the Company's finite-lived intangible assets held as of December 31, 2021 is as follows (in thousands):

For the years ending December 31,	Amortization expense
2022	$ 27,897
2023	27,186
2024	22,550
2025	8,230
2026	8,667
Thereafter	4,125
Total	$ 98,655

Other current liabilities

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

	December 31,	
	2021	2020
Customer incentives and rebates	$ 15,916	$ 15,663
Accrued other taxes payable	10,218	2,157
Deferred revenue	1,922	3,733
Derivative liabilities	269	3,061
Payables under transition services agreements	10,927	—
Other	17,476	7,676
Total other current liabilities	$ 56,728	$ 32,290

Note 3. Debt

Convertible Notes

In December 2014, the Company issued $172.5 million aggregate principal amount of Convertible Notes. During 2020, the remaining aggregate principal amount of $13.1 million was settled or matured and as of December 31, 2020 no amounts were outstanding.

The following table summarizes the interest expense related to the Convertible Notes for the following periods (in thousands):

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

The following table summarizes information about the settlement of the Convertible 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 Note and Derivative Liability	$ 43,446

Revolving Credit Facility

On August 31, 2018, the Company entered into the Credit Agreement, which provides the Company with a $175.0 million Revolving Credit Facility. No balance was outstanding as of December 31, 2021 or 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, 2021.

Interest expense recognized on the Credit Agreement, including amortization of deferred issuance cost, was $0.7 million, $0.7 million, and $1.7 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Note 4. Income Taxes

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

	December 31,		
	2021	2020	2019
Current:			
Federal	$ 148,827	$ 198,498	$ 1,559
State	42,377	34,608	746
Foreign	2,291	1,136	2,007
Total current provision	193,495	234,242	4,312
Deferred:			
Federal	7,168	(2,855)	1,234
State	(2,540)	(1,104)	(1,186)
Foreign	(1,990)	(251)	(103)
Total deferred provision (benefit)	2,638	(4,210)	(55)
Provision for income taxes	$ 196,133	$ 230,032	$ 4,257

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

	December 31,		
	2021	2020	2019
United States	$ 891,261	$ 1,035,752	$ 70,606
Foreign	9,098	4,567	6,572
Income before income taxes	$ 900,359	$ 1,040,319	$ 77,178

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2021 and 2020 are shown below (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Lease liability	$ 32,692	$ 24,790
Intangible assets	2,226	2,747
Allowance for returns and discounts	25,661	27,277
Stock-based compensation	9,171	8,367
Tax credit carryforwards	10,697	11,770
Other, net	15,486	10,426
Total deferred tax assets	95,933	85,377
Valuation allowance for deferred tax assets	(2,327)	(2,281)
Total deferred tax assets, net of valuation allowance	93,606	83,096
Deferred tax liabilities:		
Right-of-use assets	(30,114)	(22,969)
Intangible assets	(946)	(1,133)
Property, plant and equipment	(42,457)	(14,232)
Total deferred tax liabilities	(73,517)	(38,334)
Net deferred tax assets	$ 20,089	$ 44,762

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, 2021, 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, 2021, the valuation allowance did not materially change from the prior year.

The valuation allowance of $2.3 million as of December 31, 2021 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, 2021, 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 credit carryforwards. 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 $11.8 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, 2021, 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 for income taxes from continuing operations was as follows (in thousands):

	Year ended December 31,		
	2021	2020	2019
Tax expense at statutory tax rate	$ 189,081	$ 218,467	$ 16,207
State tax expense, net of federal tax	30,147	30,289	1,061
Permanent differences	1,834	3,843	611
Federal and state research credits—current year	(7,717)	(5,037)	(4,269)
Stock-based compensation	(9,235)	(13,867)	(10,408)
Change in valuation allowance	(103)	(72)	523
Foreign Derived Intangible Income Deduction (FDII)	(8,419)	(8,589)	(159)
Other	545	4,998	691
Provision for income taxes	$ 196,133	$ 230,032	$ 4,257

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,		
	2021	2020	2019
Beginning balance	$ 22,557	$ 17,236	$ 15,245
Increases (decreases) related to prior year tax positions	478	(2,351)	287
Increases related to current year tax positions	968	7,726	2,209
Decreases from voluntary disclosure agreements	(6,338)	—	—
Expiration of statute of limitations for assessment of taxes	—	(54)	(505)
Ending balance	$ 17,665	$ 22,557	$ 17,236

As of December 31, 2021, 2020 and 2019, the Company had unrecognized tax benefits of $17.7 million, $22.6 million, and $17.2 million, respectively, of which $11.3 million, $15.0 million and $11.1 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 of 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 $1.2 million as of December 31, 2021, $0.5 million as of December 31, 2020 and $0.4 million as of December 31, 2019. Interest expense, net of accrued interest (reversed) for the years ended December 31, 2021, 2020 and 2019 was approximately $0.7 million, $0.1 million and $0.1 million, respectively.

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

As of December 31, 2021, the Company no longer has any federal NOL 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 NOLs 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 planning to request refunds for payroll taxes paid during 2020 as allowed under the Employee Retention Tax Credit program and has benefited from the technical amendments regarding retroactive accelerated income tax depreciation on certain of its leasehold improvement assets.

Note 5. Stockholders' Equity

Preferred Stock. The Company's certificate of incorporation, as amended, authorizes the issuance of up to 5.0 million shares of preferred stock. The Board 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, 2021, 2020 or 2019.

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 non-employee directors. Stock options granted under these plans have terms ranging up to ten years, have exercise prices ranging from $15.40 to $254.00 per share, and generally vest over four years. As of December 31, 2021, approximately 1.9 million shares of common stock remained available for grant and 3.2 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 and directors. Until the restrictions lapse, ownership of the affected RSUs granted to the Company's officers and directors is conditional upon continuous employment with the Company.

For the years ended December 31, 2021, 2020 and 2019, the Company granted approximately 0.1 million, 0.2 million and 0.3 million shares of common stock, respectively, of RSUs to certain officers and directors, which either have a time-based, four-year vesting provision or performance-based vesting provision.

During the years ended December 31, 2021, 2020 and 2019, RSUs were granted to certain members of the Board 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 was $0.6 million, $0.5 million and $0.5 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Employee Deferred Bonus Compensation Program. For the years ended December 31, 2021, 2020 and 2019, 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 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 ESPP, full-time employees were allowed to purchase common stock through payroll deductions (which could not 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, 2021, 56,623 shares of common stock remained available for future issuance.

Share Repurchase Program. On December 12, 2018, the Board authorized a stock repurchase program, allowing the Company to repurchase up to $50.0 million of its common stock. On August 28, 2020, the Board approved an amendment to the stock repurchase program that authorized repurchases of an additional $150.0 million of the Company's common stock through August 28, 2022. During the years ended December 31, 2021 and 2020, 957,239 and 257,329 shares of outstanding common stock were repurchased under the Company's stock repurchase program. As of December 31, 2021, the Company had approximately $52.9 million available under the stock repurchase program.

Note 6. Stock-Based Compensation

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

	Year ended December 31,		
	2021	2020	2019
Cost of sales	$ 2,665	$ 2,012	$ 1,162
Research and development	4,434	3,372	2,332
Sales and marketing	6,438	6,009	3,497
General and administrative	11,869	9,626	6,261
Total stock-based compensation expense	$ 25,406	$ 21,019	$ 13,252

For the years ended December 31, 2021, 2020 and 2019, the Company recorded $3.0 million, $2.2 million and $1.4 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 5. During the years ended December 31, 2021, 2020 and 2019, $2.8 million, $2.1 million and $0.8 million, respectively, were 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,		
	2021	2020	2019
Risk-free interest rate	0.48 %	1.18 %	2.51 %
Expected option life (in years)	4.99	5.12	5.68
Volatility rate	54 %	41 %	39 %
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 common stock. The risk-free interest rate is based on the US 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 $106.55, $36.84 and $23.67 for options granted during the years ended December 31, 2021, 2020 and 2019, respectively. The total intrinsic value was $9.9 million, $51.8 million and $49.8 million for options exercised during the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, total unrecognized compensation expense related to stock options was approximately $8.7 million and the related weighted-average period over which it is expected to be recognized is approximately 1.8 years. The maximum contractual term of the Company's stock options is ten years.

A summary of stock option activity for the years ended December 31, 2019, 2020 and 2021 is as follows (dollars in thousands, except price data):

	Number of Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
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		
Granted	58	232.75		
Exercised	(90)	38.28		
Forfeited	(6)	94.44		
Outstanding at December 31, 2021	722	$ 62.71	6.02	$ 59,339
Vested and expected to vest at December 31, 2021	709	$ 61.35	5.98	$ 58,881
Exercisable at December 31, 2021	448	$ 34.51	4.91	$ 45,376

Restricted Stock Units

A summary of RSU activity for the years ended December 31, 2019, 2020 and 2021 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
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
Granted	137	$ 188.06
Vested	(414)	$ 49.00
Forfeited	(14)	$ 106.11
Non-vested at December 31, 2021	587	$ 95.81

The total amount of unrecognized compensation expense related to non-vested RSUs as of December 31, 2021 was approximately $30.8 million, which is expected to be recognized over a weighted-average period of approximately 1.6 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 Convertible 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 common shares from the Convertible Notes are determined using the if-converted method. Under the provisions of the if-converted method, the Convertible 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 Notes is added back to net income. The Convertible 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 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,		
	2021	2020	2019
Numerator:			
Net income used for basic earnings per share	$ 704,226	$ 810,287	$ 72,921
Interest expense on Convertible Notes, net of tax	—	445	1,848
Net income used for diluted earnings per share, if-converted method	$ 704,226	$ 810,732	$ 74,769
Basic weighted-average common shares outstanding	42,078	42,124	40,860
Dilutive potential shares issuable from Convertible Notes	—	295	1,062
Dilutive potential shares issuable from stock options and unvested RSUs	796	1,172	1,189
Diluted weighted-average common shares outstanding, if-converted	42,874	43,591	43,111
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	153	10	199

Potentially dilutive common 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

The Company leases 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 were as follows (in thousands):

	Year ended December 31,	
	2021	2020
Finance lease ROU asset amortization	$ 282	$ 303
Finance lease interest expense	657	877
Total finance lease costs	939	1,180
Operating lease costs	15,361	11,236
Total lease costs	$ 16,300	$ 12,416
Cash paid for amounts included in the measurement of operating lease liabilities		
Operating cash flows from operating leases	$ 12,347	$ 10,801
Operating cash flows from finance leases	$ 657	$ 877
ROU assets obtained in exchange for new lease liabilities		
Operating leases	$ 37,349	$ 15,271
Finance leases	$ —	$ —

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable leases at the end of 2021 were as follows (dollars in thousands):

Years ending December 31,	Operating	Finance
2022	$ 15,468	$ 272
2023	15,529	297
2024	15,639	99
2025	15,736	—
2026	16,057	—
Thereafter	116,835	—
Total lease payments	195,264	668
Less: imputed interest	(38,366)	(32)
Less: tenant improvement allowance (receipt anticipated in 2022)	(18,303)	—
Total	138,595	636
Less: current portion	(10,039)	(275)
Non-current portion	$ 128,556	$ 361
Weighted average remaining lease term	11.7 years	3.3 years
Weighted average discount rate	4 %	4 %

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 in October 2022, subject to an option to renew for a two-year period.

McKellar Court Lease — During 1999, the Company completed a sale and leaseback transaction of its San Diego facility at McKellar Court to 10165 McKellar Court, L.P. (“McKellar LP” or the “partnership”) for which the Company was the limited partner. McKellar LP owned the real property and improvements located at 10165 McKellar Court (the “McKellar Property”). The partnership was deemed to be a variable interest entity (“VIE”). The Company was not, however, the primary beneficiary of the VIE as it did not have the power to direct the activities of the partnership and did not have the obligation to absorb losses or receive benefits of the partnership that could potentially be significant to the partnership. The Company’s primary use of the McKellar Property is for manufacturing and administrative offices.

On August 17, 2021, a wholly owned subsidiary of the Company purchased the general partner's interest (the "GP interest") in McKellar LP for a net purchase price of $28.9 million, which was acquired using cash on hand. As a result of the purchase of the GP interest, the partnership is now a wholly owned subsidiary of the Company. The partnership continues to be a VIE for which the Company is now the primary beneficiary. The Company accounted for the GP interest as an asset acquisition and recorded building and land with a total value of $28.9 million. Prior to the purchase date, the Company was leasing the McKellar Property through 2030, with options to extend for two additional five-year periods. As a result of the Company's purchase of the GP interest in McKellar LP, the Company no longer makes lease payments for the McKellar Property. Prior to the acquisition, the Company made lease payments to the partnership of approximately $0.6 million, $1.0 million and $1.0 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Rutherford Lease — During January 2021, the Company entered into a lease agreement for a manufacturing facility in Carlsbad, California and recorded a ROU asset and a corresponding lease liability of approximately $39.4 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 $3.4 million in firm inventory purchase commitments as of December 31, 2021, the majority of which is expected to be purchased in the next one to three years.

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 alleged that a provision of an agreement between the Company and Beckman violated state antitrust laws. The Company's acquisition of the BNP Business in October 2017 consisted of assets and liabilities relating to a contractual arrangement with Beckman (the "BNP Supply 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. In the lawsuit, Beckman asserted that an exclusivity provision violated certain state antitrust laws and was unenforceable. From the inception of the lawsuit, the lawsuit was subject to numerous motions, rulings, appellate reviews and opinions. The matter was scheduled for trial starting April 15, 2022.

On July 24, 2021, the Company and Beckman entered into a Master Agreement (the "Master Agreement") pursuant to which, among other matters, the Company's business of selling and distributing the BNP test for the BNP Business will be transitioned to Beckman. Concurrent with entering into the Master Agreement, the Company and Beckman entered into a Settlement Agreement to resolve all disputes relating to the existing BNP Supply Agreement, among other matters. On August 3, 2021, the lawsuit was dismissed with prejudice.

As consideration for the arrangements during each of calendar years 2022 through and including 2029, the Company will receive a minimum payment of $70.0 million and a maximum payment of $75.0 million. Such maximum payments were pro-rated for 2021, based on the period commencing on the date of the initial commercial transition to Beckman, through December 31, 2021. In addition, the parties entered into other related agreements under the Master Agreement, including a Transition Services Agreement, pursuant to which the parties will provide various transitional services, a Supply Agreement for the supply by the Company of its antibody and other components used in the manufacture of the BNP test, and a Distribution Agreement, granting Beckman the right to sell and distribute the BNP test as described above.

From time to time, the Company is involved in other litigation and legal proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to its 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 the Company is not able to estimate a possible loss or range of loss, the Company is not able to determine whether the loss will have a material adverse effect on its business, financial condition, results of operations or liquidity. No accrual has been recorded as of December 31, 2021 and December 31, 2020 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 $2.0 million, $2.4 million and $1.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Note 9. Segment, Revenue and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the US represented 17%, 13% and 33% of total revenue for the years ended December 31, 2021, 2020 and 2019, respectively, of which sales to customers in China comprised 3%, 4% and 13%, respectively. As of December 31, 2021 and 2020, net accounts receivable due from foreign customers were $53.5 million and $18.6 million, respectively. For the years ended December 31, 2021 and 2020, sales of the Company's COVID-19 products accounted for 75% and 70%, respectively, of total revenue. For the years ended December 31, 2021, 2020 and 2019, sales of the Company's influenza products accounted for 4%, 8% and 26%, respectively, of total revenue.

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

	Year ended December 31,		
	2021	2020	2019
Customer:			
A	24 %	29 %	13 %
B	9 %	16 %	18 %
C	9 %	13 %	5 %
D	7 %	10 %	15 %
	49 %	68 %	51 %

As of December 31, 2021 and 2020, net accounts receivable from individual customers with balances due in excess of 10% of total accounts receivable totaled $267.3 million and $411.7 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,		
	2021	2020	2021	2020	2019
Domestic	$ 347,132	$ 108,375	$ 1,415,413	$ 1,452,329	$ 358,381
Foreign	2,070	2,106	283,138	209,339	176,509
Total	$ 349,202	$ 110,481	$ 1,698,551	$ 1,661,668	$ 534,890

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

	Year ended December 31,		
	2021	2020	2019
Rapid Immunoassay	$ 1,197,459	$ 1,144,831	$ 191,736
Cardiometabolic Immunoassay	255,788	242,933	266,505
Molecular Diagnostic Solutions	200,487	222,964	21,716
Specialized Diagnostic Solutions	44,817	50,940	54,933
Total revenues	$ 1,698,551	$ 1,661,668	$ 534,890

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, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	$204,672	$ 6,649	$ —	$211,321	$200,003	$ —	$ —	$200,003
Marketable securities	—	63,610	—	63,610	—	—	—	—
Derivative assets	—	84	—	84	—	24	—	24
Total assets measured at fair value	$204,672	$ 70,343	$ —	$275,015	$200,003	$ 24	$ —	$200,027
Liabilities:								
Derivative liabilities	$ —	$ 269	$ —	$ 269	$ —	$ 3,061	$ —	$ 3,061
Contingent consideration	—	—	6,073	6,073	—	—	11,896	11,896
Deferred consideration	—	78,436	—	78,436	—	115,951	—	115,951
Total liabilities measured at fair value	$ —	$ 78,705	$ 6,073	$ 84,778	$ —	$ 119,012	$ 11,896	$130,908

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, 2021 and 2020.

Cash equivalents consist of funds held in money market accounts that are valued using quoted prices in active markets for identical instruments and highly liquid corporate debt securities with maturities within three months from purchase. Marketable securities consist of investment-grade corporate debt securities, asset-backed securities and US Treasury securities. Derivative financial instruments are based on observable inputs that are corroborated by market data. Observable inputs include broker quotes, daily market foreign currency rates and forward pricing curves.

In connection with the acquisition of the BNP Business, the Company will pay annual installments of up to $48.0 million each through April 2023. 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 the contingent consideration is calculated using a discounted probability weighted valuation model. Discount rates used in such calculation are a significant assumption that are 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 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 represents a Level 3 measurement. The changes in fair value of the contingent consideration during the years ended December 31, 2021, 2020 and 2019 were due to changes in the estimated payments and discounting periods.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2018 through December 31, 2021 were as follows (in thousands):

	Contingent consideration liability (Level 3 measurement)
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
Cash payments	(6,040)
Change in estimated fair value, recorded in general and administrative expenses	217
Balance at December 31, 2021	$ 6,073

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. The 401(k) Plan includes an employer match of 50% on the first 6% of pay contributed by the employee. The Company contributed approximately $3.8 million, $3.1 million and $2.5 million to the 401(k) Plan during the years ended December 31, 2021, 2020 and 2019, 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 foreign currency forward 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 the Company's exposure to credit or market loss. Credit risk represents the Company's 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. The Company generally enters into master netting arrangements that reduce credit risk by permitting net settlement of transactions with the same counterparty. The Company presents its derivative assets and derivative liabilities at their net fair values. The Company does not have any derivative instruments with credit-risk related contingent features that would require it to post collateral.

The following table summarizes the fair value and notional amounts of the foreign currency forward contracts as of December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021		December 31, 2020	
	Notional Amount	Fair Value, Net	Notional Amount	Fair Value, Net
Designated cash flow hedges:				
Prepaid expenses and other current assets	$ —	$ 84	$ —	$ —
Other current liabilities	$ 17,629	$ 139	$ 38,435	$ 2,819
Non-designated forward contracts:				
Prepaid expenses and other current assets	$ —	$ —	$ 18,160	$ 24
Other current liabilities	$ 15,809	$ 130	$ 23,120	$ 242

Note 13. Pending Business Combination

On December 22, 2021, the Company entered into the BCA with Ortho, Topco, US Holdco Sub, US Merger Sub and US Holdco Sub 2. Under the terms of the BCA, the Company is entering into the Combinations with Ortho under Topco, a new holding company. The Combinations are expected to be implemented by way of (i) the Ortho Scheme, pursuant to which each issued and outstanding Ortho Share will be acquired by a nominee of Topco, such that Ortho will become a wholly owned subsidiary of Topco, and (ii) the Quidel Merger immediately following consummation of the Ortho Scheme, with the Company surviving the merger as a wholly owned subsidiary of Topco.

At the effective time of the Ortho Scheme, each Ortho Share will be acquired by a nominee on behalf and for the benefit of Topco in exchange for 0.1055 Topco Shares and $7.14 in cash. At the effective time of the Quidel Merger, each Quidel Share will be converted into the right to receive one Topco Share. Ortho will be acquired for total consideration of approximately $4.3 billion (which is based on the February 9, 2022 closing price of $97.64 per Quidel Share), including $1.75 billion of cash, funded through cash on the Company's balance sheet and expected incremental borrowings. Following the closing of the Combinations, Ortho's current net debt of $2.1 billion is expected to continue to be outstanding.

If the Combinations are completed, Ortho shareholders are expected to own approximately 38% of Topco on a fully diluted basis and the Company's stockholders are expected to own approximately 62% of Topco on a fully diluted basis, based on the respective capitalizations of Ortho and the Company as of the date of the BCA. The parties intend to list the Topco Shares to be issued in the Combinations on Nasdaq.

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, 2021:				
Accounts receivable allowance	$ 103,435	$ 456,237	$ (507,249)	$ 52,423
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

(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 Exchange Act. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2021 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, 2021 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 GAAP. 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, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 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, 2021, 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, 2021, 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, 2021 and 2020, 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, 2021, and the related notes and schedule listed in the Index at Item 15(a)(2) and our report dated February 17, 2022 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 17, 2022

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be filed by amendment to this Annual Report or incorporated by reference to our 2022 proxy statement no later than April 30, 2022. 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 will be filed by amendment to this Annual Report or incorporated by reference to our 2022 proxy statement no later than April 30, 2022.

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

The information required by this item will be filed by amendment to this Annual Report or incorporated by reference to our 2022 proxy statement no later than April 30, 2022.

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

The information required by this item will be filed by amendment to this Annual Report or incorporated by reference to our 2022 proxy statement no later than April 30, 2022.

Item 14. Principal Accountant Fees and Services

The information required by this item will be filed by amendment to this Annual Report or incorporated by reference to our 2022 proxy statement no later than April 30, 2022.

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, 2021, 2020 and 2019 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
2.1+	Business Combination Agreement, dated as of December 22, 2021, by and among Quidel Corporation, Ortho Clinical Diagnostics Holdings plc, Coronado Topco, Inc., Laguna Merger Sub, Inc., Orca Holdco, Inc. and Orca Holdco 2, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K filed on December 23, 2021.)
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(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.)
10.11(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.)
10.12(1)	Employment Offer Letter, dated as of 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.)

Exhibit Number	Description
10.13(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.)
10.14(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.)
10.15	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.)
10.16	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.)
10.17	Summers Ridge Lease. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 9, 2018.)
10.18	Amended and Restated Credit Agreement, by and among Quidel Corporation, 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, and Bank of America Merrill Lynch and JPMorgan 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 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.)
10.19(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.)
10.20(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.)
10.21(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.)
10.22(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.)
10.23(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.)
10.24(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.)
10.25(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.)
10.26	Amendment No. 1 to Amended and Restated Credit Agreement, dated September 11, 2020. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.)
10.27	Lease Agreement by and between ARE-SD Region No. 71, LLC, as Landlord, and Quidel Corporation, as Tenant, dated as of January 14, 2021. (Incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020.)
10.28(1)	2021 Cash Incentive Compensation Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 5, 2021.)
10.29(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, 2021.)
10.30	Amendment No. 2 to Amended and Restated Credit Agreement, dated May 7, 2021. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 12, 2021.)
10.31+	Master Agreement, dated as of July 24, 2021, by and among Quidel Corporation, Quidel Cardiovascular, Inc., and Beckman Coulter, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on July 26, 2021.)
10.32(1)*	Transition Agreement between the Registrant and Karen Gibson.
10.33	Principal Stockholders Agreement, dated as of December 22, 2021, by and among Coronado Topco, Inc., Quidel Corporation, Ortho Clinical Diagnostics Holdings plc and the Initial Carlyle Stockholder (as defined therein). (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 23, 2021.)

Exhibit Number	Description
10.34(1)*	Form of Change in Control Agreement.
10.35(1)	2022 Cash Incentive Compensation Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on February 4, 2022.)
10.36(1)	2022 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 4, 2022.)
10.37(1)	Form of Success Fee Letter. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on February 4, 2022.)
10.38(1)	Form of Integration and Retention Bonus Letter. (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on February 4, 2022.)
10.39(1)*	Amendment to Individual Retirement Program for Randall Steward, dated February 1, 2022.
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 Registrant's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (iv) 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 Registrant's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL (included as Exhibit 101).

* Filed / furnished herewith

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

\+ The schedules and similar attachments to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish copies of any such schedules or similar attachments to the SEC upon request. In addition, certain provisions of this exhibit have been redacted because the Registrant customarily treats the redacted information as private or confidential and the omitted information is not material. The Registrant agrees to promptly provide to the SEC on a supplemental basis an unredacted copy of the exhibit.

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 17, 2022

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 17, 2022
/s/ RANDALL J. STEWARD Randall J. Steward	Chief Financial Officer, (Principal Financial and Accounting Officer)	February 17, 2022
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 17, 2022
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 17, 2022
/s/ KATHY P. ORDOÑEZ Kathy P. Ordoñez	Director	February 17, 2022
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 17, 2022
/s/ ANN D. RHOADS Ann D. Rhoads	Director	February 17, 2022
/s/ CHARLES P. SLACIK Charles P. Slacik	Director	February 17, 2022
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 17, 2022
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 17, 2022
/s/ JOSEPH D. WILKINS JR. Joseph D. Wilkins Jr.	Director	February 17, 2022

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QUIDEL SENIOR MANAGEMENT

Douglas C. Bryant
President and Chief Executive Officer

Randall J. Steward
Chief Financial Officer

Robert J. Bujarski
Chief Operating Officer

William J. Ferenczy
SVP, Cardiometabolic Business Unit

Michelle A. Hodges
SVP, General Counsel

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

Tamara A. Ranalli
SVP, Molecular Business Unit

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

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

Kathy P. Ordoñez
Former Chief Executive Officer of RainDance Technologies, Inc., Celera Corporation, and Roche Molecular Systems, Inc.

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 of Beckman Coulter, Inc.

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

Kenneth J. Widder, M.D.
Chief Executive Officer of Sydnexis Inc.

Joseph D. Wilkins Jr.
Managing Director of JW Healthcare Insights

Outside Legal Counsel
Gibson, Dunn & Crutcher LLP
San Francisco, California 94105

Snell & Wilmer, LLP
Phoenix, Arizona 85004

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

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

Transfer Agent & Registrar
American Stock Transfer & Trust Company LLC
6201 15th Avenue
Brooklyn, New York 11219
800.937.5449 or 718.921.8200
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
Copies of Quidel's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other reports that Quidel files with the Securities and Exchange Commission are available without charge upon request. Please contact Investor Relations.

Investor Relations
9975 Summers Ridge Road
San Diego, California 92121 USA
858.552.7955
ir@quidel.com

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

CHANGING LIVES

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QUIDEL

CHANGING LIVES

QUIDEL CORPORATION CORPORATE HEADQUARTERS

9975 Summers Ridge Road
San Diego, California 92121 USA

U.S. OPERATIONS

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

INTERNATIONAL OPERATIONS

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