Changing lives, one test at a time

2022 Annual Report

QuidelOrtho™

Our unique pure-play position keeps us vigilant to emerging diagnostic needs and opportunities, providing solutions that span the continuum of healthcare, from home to hospital, lab to clinic.

Douglas C. Bryant
President and Chief Executive Officer
QuidelOrtho

Customers, Colleagues and Fellow Stockholders,

This year, I am writing to you from our new company, QuidelOrtho Corporation. We are now a united pure-play diagnostics company, and I'd like to start with a heartfelt thanks to my colleagues who have worked so hard to make this a reality.

In May 2022, we completed our business combination with Ortho Clinical Diagnostics to transform our business into an innovative end-to-end top diagnostics player with scale and a portfolio that spans high-volume, high-complexity hospitals and labs to point-of-care, retail and over-the-counter markets.

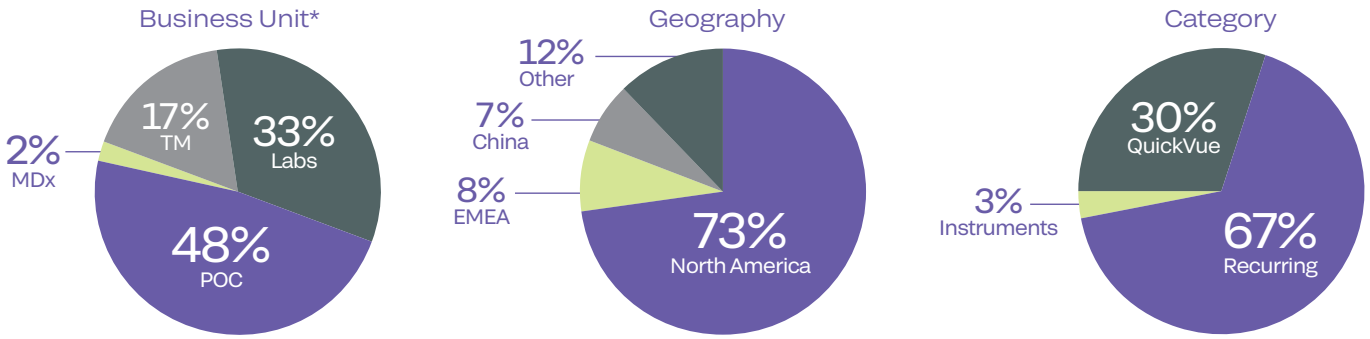
Together, we are poised for new levels of performance and growth that build upon proven track records in award-winning service, customer excellence and a robust innovation pipeline with an enhanced global commercial reach.

2022 operating review

Our financials last year demonstrated the transformative potential of the combined business. In 2022, on an as-reported basis, our global revenue increased by 92 percent, reaching $3.3 billion, excluding the first five months of Ortho's revenue prior to the combination of the two companies.

Let's look closer at the supplemental combined $4.1 billion of revenue, which was up 10 percent in constant currency.[1] Excluding COVID-19-related revenue, our supplemental combined revenue increased by 11 percent in constant currency.[1] Our strong diversified diagnostics business, driven by our Labs, Point of Care, Transfusion Medicine and Molecular Diagnostics business units, demonstrated the resiliency in our business model even with temporary macro challenges that affected some areas of our business. Those challenges, including COVID-19-related lockdowns in China and global supply chain, which mainly affected our Labs business unit, are now either behind us or are expected to alleviate as we move through 2023, setting the stage for sustainable high-single-digit growth over the coming years.

1. Constant currency is a non-GAAP financial measure and is not meant to be considered in isolation from or as a substitute for financial information prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). See reconciliations of non-GAAP measurements to their most directly comparable GAAP measures at the bottom of this letter.



*MDx = Molecular Diagnostics; POC = Point of Care; TM = Transfusion Medicine

A strong and resilient foundation that can flex

Our thoughtful and disciplined approach to integrating our people, building our leadership team and refining our commercial and operational strategies creates a foundation that not only enables operational efficiency, cost synergy and company-wide alignment, but further unlocks the value and potential of our combined business. We see a dynamic world where behaviors are shifting, and practitioners and consumers are testing more frequently in more locations – QuidelOrtho is committed to meeting these challenges. Leveraging our combined strengths, we are ideally positioned to address the complex needs of a global healthcare environment where enhanced diagnostic solutions will be increasingly in demand wherever and whenever they are needed.

A clear and focused path to meaningful growth

Our expanded capabilities, expertise and global footprint allow us to reach more people and continue to exceed customer expectations across the diagnostics continuum. Our unique pure-play position keeps us vigilant to emerging diagnostic needs and opportunities. With more than 100 active research and development, clinical and regulatory projects underway, we are poised to exceed our historical track record of prolific product development.

I speak often about excellent execution being a function of things done well at speed. Achieving speed requires focus and selecting goals that are going to matter most in the moment. Although there are other projects that are also important, we believe that focusing on the following three near-term initiatives in 2023 will drive meaningful impact over the next few years.

As part of our Point of Care business unit, our sophisticated yet easy-to-use benchtop Sofia devices are used for multiple types of testing, driving market share gains in the respiratory disease category. With significant cumulative placements and the global reach of our unified commercial teams, Sofia is an immensely valuable asset that we will continue to augment through research and development efforts to expand single and combination assay menu options.

Powered by our Vitros dry slide technology and expansive product portfolio, we provide flexible and scalable solutions across a range of customer requirements – from standalone chemistry and immunoassay systems to integrated systems to fully automated solutions, predictive data and award-winning service. Our goal is to lead the way to better health for more people in more places.

- Growth in our Labs business unit is fueled by the placement of our integrated analyzers and the pull-through of higher growth, higher margin immunoassays, alongside our historical strength in clinical chemistry. Our focus on mid- and high-throughput hospital labs where we offer the lowest cost of ownership in the market, coupled with our award-winning customer service, has further added to our strength. To sustain our momentum in the near to medium term, we are planning to refresh our Vitros® systems, introduce new automation and informatics and launch approximately 20 to 25 new or refreshed assays.
- As part of our Point of Care business unit, our flagship Sofia® platform boasts a robust and expanding business with over 85,000 cumulative instrument placements globally. These sophisticated yet easy-to-use benchtop devices are used for multiple types of testing, with the majority running influenza tests (at 82 percent) and COVID-19 tests (at 70 percent). These tests continue to drive market share gains in the respiratory disease category. With significant cumulative placements and the global reach of our unified commercial teams, we consider Sofia to be an immensely valuable asset that we will continue to augment through research and development efforts that expand single and combination assay menu options for our customers.

- Our revolutionary new Savanna® molecular platform utilizes real-time PCR and syndromic panels to address a variety of pain points across the diagnostics continuum. The platform offers speed, simplicity and flexibility, making it suitable for use in multiple customer environments including physician office labs, emergency departments, pharmacy and urgent care settings as well as hospital and reference labs. Savanna is currently CE-IVDD marked and available throughout Europe, with plans to commercialize worldwide upon additional regulatory clearances. Our initial menu includes our RVP4 respiratory virus panel, followed by panels for HSV/VZV/syphilis, RVP11, sexually transmitted infections, two gastrointestinal panels (bacterial/viral and parasites), pharyngitis and vaginitis. We have focused our offerings on syndromic testing needs that take advantage of the unique features of Savanna including rapid turnaround time, simple workflow and test flexibility with Test Select.

Beyond these near-term priorities, our ability to serve the full diagnostics continuum, from home to hospital, lab to clinic, unlocks additional growth opportunities for us. As more customers demand converging capabilities and connected systems and insights, we are strategically positioned to explore and capitalize on these emerging areas.

A culture that will propel us

Powerful cultures are a commercial asset, they can be a force multiplier driving company-wide performance and growth. At QuidelOrtho, we are cultivating a culture of curiosity, boldness, integrity and happiness that motivates and inspires our people to bring their best to work every day. I firmly believe that a thriving culture genuinely benefits our people and leads to happier customers, healthier communities and ultimately a successful company with long-term sustainable growth.

At QuidelOrtho, culture does not happen by accident. We employed a strategic and intentional approach to empower each individual to thrive. We are implementing *The QuidelOrtho Way* across the organization, fostering a deeper understanding and participation in our core values and our ways of working together. Bottom line, our employees come first, and they truly are the key to our success.

Photos on the following page

Clockwise from top right:

John Canton and Kevin Canton

North Kanto Sales Office
Back row left to right: Norikazu Shima, Daiki Uehara, Naoki Inoue, Tatsuro Nakabayashi. Middle row: Kenji Narita, Karin Tenjin, Yoshihiro Shiiba, Masahiro Yoshida. Front row: Shigeo Kamakura, Furuse Masahiro, Yuki Sotoyama

Go Red for Women Luncheon
Danielle Hamann and Louise Brandy

Marco Bartoloni, Elga Canducci, Rocco Calcagno

Left to right: Stephanie Kleewein, Lisa Wiesner, Lisa Hayes, Danyelle Taylor, Jennifer Camps, Tammy Lambdin, Tara Briggs, Scott Bain, Shellie Ruth, Steve Levins, Beth Slavic, Joe Vona, Jeannine Mason

Our revolutionary new Savanna molecular platform utilizes real-time PCR and syndromic panels to address a variety of pain points across the diagnostics continuum. The platform offers speed, simplicity and flexibility, making it suitable for use in multiple customer environments including physician office labs, emergency departments, pharmacy and urgent care settings, as well as hospital and reference labs. Savanna is currently CE-IVDD marked and available throughout Europe, with plans to commercialize worldwide upon additional regulatory clearances.

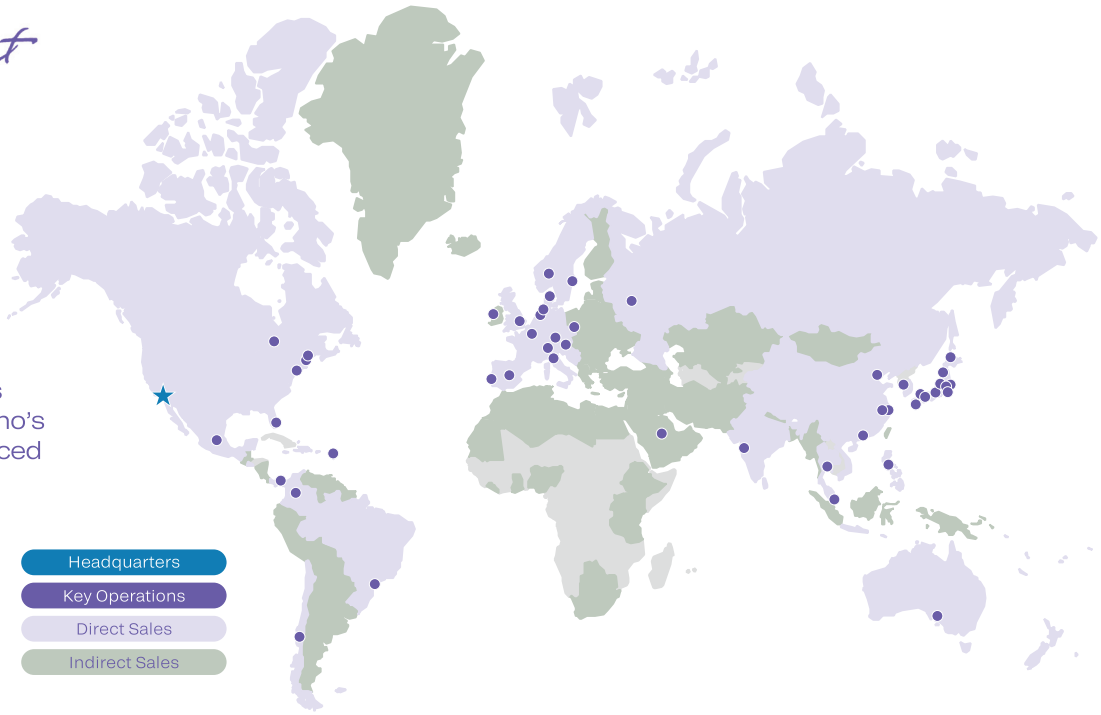
At QuidelOrtho, we are cultivating a culture of curiosity, boldness, integrity and happiness that motivates and inspires our people to bring their best to work every day.

In summary, I have always considered this organization to be special and I am immensely proud of what we have built over the past year. As a united QuidelOrtho, we are a place like no other. **We are a stable company that can flex**, able to take on smart investments and respond with speed to meet the needs of a dynamic marketplace. **We are a growth company**, acutely focused on those areas that can bring the healthiest return and sustainable growth. And **we are a culture-driven company** that inspires each of us to push, question, shift paradigms and create life-changing technologies, so **we can transform the power of diagnostics and improve countless lives along the way**.

I am confident in our ability to accelerate and sustain our growth profile over the long term, to grow at or above our markets, and as we do so, create consistent value for our customers, colleagues and fellow stockholders. It is an honor to stand alongside my colleagues and a true privilege to be part of QuidelOrtho. Together, we are taking this organization to the next level in making diagnostics available to more patients in more places around the world, from home to hospital, lab to clinic.

Sincerely,

Douglas Bryant



Forward-looking statements

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. You can identify these statements in this document by words such as "may," "will," "would," "expect," "anticipate," "believe," "estimate," "plan," "intend," "continue" or similar words, expressions or the negative of such terms or other comparable terminology. These statements include, but are not limited to, the benefits and results of the business combination and integration of the businesses of Quidel Corporation ("Quidel") and Ortho Clinical Diagnostics ("Ortho"), including QuidelOrtho's execution of commercial, integration and other strategic goals, future financial and operating results, future plans, objectives, strategies, expectations and intentions and other statements that are not historical facts. Such statements are based on the beliefs and expectations of QuidelOrtho's management as of today and are subject to significant risks and uncertainties. Actual results may differ significantly from those set forth or implied in the forward-looking statements. The following factors, among others, could cause actual results to differ from those set forth or implied in the forward-looking statements: the challenges and costs of integrating, restructuring and achieving anticipated synergies as a result of the business combination; the ability to retain key employees; and other economic, business, competitive and/or regulatory factors affecting the business of QuidelOrtho generally. Additional risks and factors are identified under "Risk Factors" in QuidelOrtho's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "Commission") on February 23, 2023 and subsequent reports filed with the Commission. You should not rely on forward-looking statements as predictions of future events because these statements are based on assumptions that may not come true and are speculative by their nature. QuidelOrtho has no obligation to update any of the forward-looking information or time-sensitive information included in this document, whether as a result of new information, future events, changed expectations or otherwise, except as required by law. All forward-looking statements are based on information currently available to QuidelOrtho and speak only as of the date hereof.

Non-GAAP financial measures

This document contains "constant currency revenue growth," which is considered a non-GAAP financial measure under applicable rules and regulations of the Commission. This non-GAAP financial measure should be considered supplemental to, and not a substitute for, financial information prepared in accordance with GAAP. QuidelOrtho's definition of this non-GAAP measure may differ from similarly titled measures used by others. This non-GAAP financial measure reflects an additional way of viewing aspects of QuidelOrtho's operations that, when viewed with GAAP results and the reconciliations to corresponding GAAP financial measures, may provide a more complete understanding of factors and trends affecting QuidelOrtho's business. Because non-GAAP financial measures exclude the effect of items that will increase or decrease QuidelOrtho's reported results of operations, management strongly encourages investors to review QuidelOrtho's consolidated financial statements and reports filed with the Commission in their entirety. A reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure is included in the following table.

Reconciliation of Non-GAAP Financial Information

	Fiscal Year Ended						
	January 1, 2023	January 2, 2022	% Change	Currency Impact	Constant Currency [a]	Less: COVID-19 revenue impact	Constant Currency, ex COVID-19 revenue
Labs	$ 1,331.2	$ 1,423.4	(6.5)%	(2.3)%	(4.2)%	2.6 %	(1.6)%
Transfusion Medicine	668.1	664.2	0.6 %	(4.8)%	5.4 %	— %	5.4 %
Point of Care	1,955.2	1,453.3	34.5 %	(0.6)%	35.1 %	31.9 %	67.0 %
Molecular Diagnostics	96.7	200.5	(51.8)%	(0.3)%	(51.5)%	78.3 %	26.8 %
Total supplemental combined revenues	$ 4,051.2	$ 3,741.4	8.3 %	(2.0)%	10.3 %	0.8 %	11.1 %

Supplemental combined revenues include Ortho revenues on a pro forma basis as if the acquisition had occurred on January 4, 2021, and are in accordance with Regulation S-X Article 11 and Accounting Standards Codification 805, Business Combinations.

(a) The term "constant currency" means we have translated local currency revenues for all reporting periods to U.S. dollars using currency exchange rates held constant for each year. This additional non-GAAP financial information is not meant to be considered in isolation from or as substitute for financial information prepared in accordance with GAAP.

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 January 1, 2023

OR

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

For the transition period from _____ to _____

Commission file number: 001-41409

QUIDELORTHO CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**87-4496285**
(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 (§ 232.405 of this chapter) 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 internal 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 $6,008,202,595 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 10, 2023, 66,505,546 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

(To the Extent Indicated Herein)

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2023 Annual Meeting of Stockholders (scheduled to be held on May 16, 2023) are incorporated by reference into Part III, Items 10, 11, 12, 13 and 14 of this Annual Report on Form 10-K.

QUIDELORTHO CORPORATION

FORM 10-K

FOR THE FISCAL YEAR ENDED JANUARY 1, 2023

TABLE OF CONTENTS

Future Uncertainties and Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Without limiting the foregoing, the words "may," "will," "would," "should," "might," "expect," "anticipate," "believe," "estimate," "plan," "intend," "goal," "project," "strategy," "future," "continue," or similar words, expressions or the negative of such terms or other comparable terminology are intended to identify forward-looking statements. These statements include any statements contained herein that are not statements of historical fact, including, but not limited to, 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 our commercial, integration and other strategic or sustainability-related goals, industry prospects, expected results of operations or financial position, and future plans, objectives, strategies, expectations and intentions. Such statements are based on the beliefs and expectations of our management as of the date of this Annual Report and are subject to significant risks and uncertainties. Actual results or outcomes may differ significantly from those set forth or implied in the forward-looking statements. The following factors, among others, could cause actual results to differ from those set forth or implied in the forward-looking statements: the challenges and costs of integrating, restructuring and achieving anticipated synergies as a result of the Combinations (as defined in this Annual Report); the ability to retain key employees; and other economic, business, competitive and/or regulatory factors affecting our business generally, including those discussed under Part I, Item 1A, "Risk Factors." Investors should not rely on forward-looking statements as predictions of future events because these statements are based on assumptions that may not come true and are speculative by their nature. We have no obligation to update any of the forward-looking information or time-sensitive information included in this Annual Report, whether as a result of new information, future events, changed expectations or otherwise, except as required by law. All forward-looking statements are based on information currently available to us and speak only as of the date of this Annual Report.

Part I

Item 1. Business

All references to "the Company," "we," "our" and "us" in this Annual Report refer to QuidelOrtho Corporation ("QuidelOrtho") and its subsidiaries. References to "fiscal year 2022" in this Annual Report refer to the Company's fiscal year ended January 1, 2023.

Overview

Our mission is to develop and manufacture intelligent diagnostic solutions that transform the power of diagnostics into a healthier future for everyone. Our expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine helps clinicians and patients make better informed decisions across the globe. Our global infrastructure and commercial reach support our customers across more than 130 countries and territories with quality diagnostics, a broad test portfolio and market-leading service. We operate globally with manufacturing facilities in the U.S. and U.K. and with sales centers, administrative offices and warehouses located throughout the world.

We currently sell our products directly to end users through a direct sales force and through a network of distributors, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other point-of-care ("POC") settings, blood banks and donor centers, as well as for individual, non-professional, over-the-counter ("OTC") use. We reached significant new markets as we introduced our QuickVue® At-Home OTC COVID-19 test for at-home consumer use, school districts, health departments and many other locations.

On May 27, 2022, pursuant to a Business Combination Agreement entered into as of December 22, 2021 (the "BCA"), by and among Quidel Corporation ("Quidel"), Ortho Clinical Diagnostics Holdings plc ("Ortho"), QuidelOrtho (formerly Coronado Topco, Inc.), Orca Holdco, Inc., Laguna Merger Sub, Inc. ("U.S. Merger Sub"), and Orca Holdco 2, Inc., Quidel and Ortho consummated a business combination (the "Combinations") by way of (i) a scheme of arrangement undertaken by Ortho under Part 26 of the U.K. Companies Act 2006 (the "Ortho Scheme"), pursuant to which each issued and outstanding share of Ortho was acquired by a nominee of QuidelOrtho, such that Ortho became a wholly owned subsidiary of QuidelOrtho, and (ii) a merger of U.S. Merger Sub with and into Quidel, with Quidel surviving the merger as a wholly owned subsidiary of QuidelOrtho. The High Court of Justice of England and Wales (the "Court") sanctioned the Ortho Scheme on May 26, 2022 and a sealed order of the Court was delivered to the Registrar of Companies at Companies House on May 27, 2022, satisfying the final condition to closing of the Combinations.

Beginning in the second quarter of 2022, in connection with the Combinations and in order to manage our business to better align with the market dynamics of the specific geographic regions in which we operate, we changed the manner in which we review our performance and allocate resources. As a result, we changed from one reportable segment to the following three geographically-based reportable segments: North America; Europe, the Middle East and Africa ("EMEA"); and China. Latin America, Japan and Asia Pacific are immaterial operating segments that are not considered reportable segments and are included in "Other." We generate our revenue primarily in the following business units: Labs, Transfusion Medicine, Point of Care and Molecular Diagnostics. Information concerning revenues attributable to our reportable segments and business units is set forth in Note 4 and Note 5 to the Consolidated Financial Statements.

Business Units and Products

In connection with the Combinations, we reorganized our former product categories into four business units. Revenues from our former Specialized Diagnostic Solutions product category have been included in a new Labs business unit described below. Our former Rapid Immunoassay and Cardiometabolic Immunoassay product categories now represent our Point of Care business unit. The Molecular Diagnostics business unit represents the former Molecular Diagnostic Solutions product category. In addition, we added a Transfusion Medicine business unit.

We provide diagnostic testing solutions under various brand names, including, among others, the following: AdenoPlus™, BIOVUE®, D3®, ELVIRA®, ELVIS®, FastPoint®, FreshCells™, InflammaDry®, Lyra®, MicroVue™, Ortho®, Ortho Clinical Diagnostics®, Ortho Vision™, Quidel®, QuickVue, QuickVue+®, QVue™, ReadyCells®, Savanna®, Sofia®, Solana®, Thyretain®, Triage®, Virena® and Vitros®. Solely for convenience, in some cases, the trademarks, service marks and trade names referred to in this Annual Report are listed without the applicable ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to these trademarks, service marks and trade names.

Following the Combinations, we generate product revenue in the following business units:

Business Unit	Focus
Labs	Clinical chemistry laboratory instruments and tests, which measure target chemicals in bodily fluids for the evaluation of health and the clinical management of patients
	Immunoassay laboratory instruments and tests, which measure proteins as they act as antigens in the spread of disease, antibodies in the immune response spurred by disease, or markers of proper organ function and health
	Testing to detect and monitor disease progression across a broad spectrum of therapeutic areas
	Other product revenues primarily from contract manufacturing
	Specialized diagnostic solutions
	Collaboration and license agreements pursuant to which we derive collaboration and royalty revenues
Molecular Diagnostics	Tests for Polymerase Chain Reaction ("PCR") thermocyclers with reduced process time and ready-to-use reagent configurations
	Molecular amplification systems with the ability to run multiple assays at the same time and tests for infectious disease diagnostics
	Sample-to-result molecular instruments and tests for syndromic infectious disease diagnostics
Point of Care	Instruments and tests to provide rapid results across a broad continuum of POC settings, including tests for professional healthcare providers and tests that can be taken at home
	Tests that are run on a range of portable, POC analyzers
	Tests that are visually read
Transfusion Medicine	Immunohematology instruments and tests used for blood typing and antibody identification to help ensure patient-donor compatibility in blood transfusions
	Donor screening instruments and tests used for blood and plasma screening for infectious diseases for global customers

The products and platforms under each business unit are described below. Certain products and platforms are not available in all regions where we do business.

LABS	
Product	**Primary Application**
Virology	Wide variety of traditional cell lines, specimen collection devices, media and controls for use in laboratories that culture and test for human viruses, including, among others, respiratory and herpes family viruses
	Cell-based products under the FreshCells brand in multiple formats, including tubes, shell vials and multi-well plates
	U.S. Food and Drug Administration ("FDA")-cleared bioassay, Thyretain, which is used for the differential diagnosis of an autoimmune disease called Graves' Disease
Specialty Products	Variety of biomarkers for bone health
	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
	Enzyme-linked immunosorbent assays and reagents for the detection of activation products from the three main complement pathways in autoimmune disease
	Assays developed on a microwell platform and marketed to clinicians and researchers under the Quidel and MicroVue brands
Clinical Chemistry	Unique, postage-stamp-sized, dry slide technology that combines the spreading, masking, scavenger and reagent layers into one slide, which provides:
	• high-quality results quickly, efficiently and economically;
	• improved storage, with longer shelf life and less shelf space required;
	• an eco-friendly design that eliminates water usage and reduces chemical waste and biohazards; and
	• a comprehensive menu covering 24 therapeutic areas and approximately 90% of a typical laboratory's testing needs
Immunodiagnostics	Enhanced chemiluminescent technology provides precision and accuracy along with a wide, dynamic testing range across over 60 immunoassay tests. Reagents are packaged in ready-to-use integrated packs that can be loaded continuously while testing is underway for high-throughput applications. These integrated packs also feature extended on-analyzer stability, enabling lower-throughput labs to maintain a broader test menu without incurring reagent waste due to expiry.
VITROS Platform	Seven clinical chemistry, immunoassay and integrated (combined chemistry and immunoassay) systems for use in centralized, higher-throughput (hospitals and laboratories) and decentralized, lower-throughput (physician offices, clinics and specialty settings) testing sites
VITROS XT Platform	VITROS XT 7600 integrated system and VITROS XT 3400 clinical chemistry analyzer for use with new XT chemistry slides, combining two tests that are frequently used together, offering advancements over prior generations:
	• 40% greater test throughput when using XT slides;
	• 96% first-pass yield on test results; and
	• designed to offer high reliability with a 98% up-time guarantee for e-connected U.S. customers
VITROS Automation Solutions	A flexible and scalable track-based system that combines VITROS analyzers with a number of robotic modules to help laboratories enhance their operations by reducing or eliminating repetitive and redundant laboratory tasks and the total number of human interventions required to complete typical laboratory testing
Testing Menu	
Anemia, Bone Disease, Cardiac, Diabetes, Drugs of Abuse, General Chemistry, Hepatic, Immunosuppressant Drugs, Infectious Diseases, Inflammatory, Lipids, Nutritional Assessment, Oncology, Pancreatic, Prenatal, Renal, Reproductive Endocrinology, Respiratory, Sepsis, Spinal, Therapeutic Drug Monitoring, Thyroid/Metabolic, Toxicology, Urine	

MOLECULAR DIAGNOSTICS	
Product	**Primary Application**
Lyra	Open platform, real-time PCR assays for high throughput, high quality molecular testing to detect and identify infectious diseases, offering room-temperature storage, reduced processing time, and ready-to-use reagent configurations
Solana	Simplified molecular testing platform using our proprietary isothermal helicase-dependent amplification ("HDA") technology that is easy to run and can process 12 patient samples at the same time
Savanna	CE-marked, multiplex, real-time PCR platform, with customizable flexible syndromic panels that run up to 12 unique analytes from a single patient sample in less than 25 minutes
	Savanna RVP4 assay offers 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
Testing Menu	
Adenovirus, Bordetella, Clostridium Difficile (organism), HSV 1+2/VZV, Influenza A+B, Parainfluenza Virus, RSV, Respiratory Viral Panel (Flu A+B, RSV, hMPV), Respiratory Viral Panel 4 (Flu A+B), SARS-CoV-2, Strep A, Strep B, Strep Complete, Trichomonas	

POINT OF CARE	
Product	**Primary Application**
Rapid Immunoassay	
Sofia, Sofia 2 and Sofia Q	Easy-to-use, rapid testing using lateral-flow technology and advanced fluorescent immunoassay ("FIA") chemistry
	Combines unique software and Sofia FIA tests to yield automatic, objective results that are 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
	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, such as enhanced optics for improved performance and speed, at a cost point that better addresses the lower-volume segment of the diagnostic testing market
	Emergency use authorization ("EUA") to market Sofia Q platform that offers similar features and benefits as the other Sofia analyzers in a smaller and less expensive format
QuickVue	Broad portfolio of rapid, visually read, lateral flow immunoassay products to diagnose a wide variety of infectious diseases and medical conditions, including the QuickVue At-Home OTC COVID-19 test, a leading at-home COVID-19 product available through many retail and online outlets
InflammaDry and AdenoPlus	Rapid, lateral-flow-based POC products for the detection of infectious and inflammatory diseases and conditions of the eye
Cardiometabolic Immunoassay	
Triage and Triage MeterPro®	Portable, rapid testing platform offering a comprehensive menu of tests for diagnosis of critical diseases and health conditions, as well as the detection of certain drugs of abuse
	Aids in the diagnosis, assessment and risk stratification of patients having critical care issues, including congestive heart failure, acute coronary syndromes and acute myocardial infarction, and can reduce hospital admissions and improve clinical and economic outcomes
	Triage B-type Natriuretic Peptide ("BNP") test for use on Beckman Coulter ("Beckman") lab analyzers ("BNP Business") in connection with the transition of the BNP Business to Beckman
Testing Menu	
Cardiac	BNP, Creatine Kinase-MB, D-Dimer, hsTroponin, Myoglobin, Troponin I ES
Drugs of Abuse	Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone Metabolite (EDDP), Methamphetamines, Opiates, PCP, THC/Cannabinoids, Tricyclic Antidepressants
Eye Health	Acute Conjunctivitis, MMP-9 (a key inflammatory marker for dry eye)
Infectious Diseases	Adenoviral Conjunctivitis, Anti-SARS-CoV-2 IgG, Campylobacter, Chlamydia, Clostridium Difficile (organism), H. pylori Ab, H. pylori Ab (stool), Influenza A+B, Influenza A+B & SARS-CoV-2 Ag, Legionella, Lyme Disease, RSV, S. pneumoniae, Strep A
Inflammatory	Lactoferrin
Oncology	Colorectal Cancer
Reproductive Endocrinology	Human Chorionic Gonadotrophin, Placental Growth Factor

TRANSFUSION MEDICINE	
Product	**Primary Application**
Immunohematology	
ORTHO VISION Platform	Flagship immunohematology analyzers that automate blood typing, antibody identification and crossmatching for patient and donor blood banks
	Models include ORTHO VISION, ORTHO VISION Max, and next-generation ORTHO VISION Swift and ORTHO VISION Swift Max, which are designed to be faster, quieter and even more cyber-secure than previous generations
Ortho Workstation	Semi-automated immunohematology benchtop analyzer for lower-volume blood centers or centers that need semi-automated testing
Ortho Optix	Semi-automated testing platform used to read manual test results, designed with improved software and ability to integrate with laboratory information systems and offers improved workflow and 99% concordance with ORTHO VISION test results
ID-Micro Typing System (ID-MTS) Gel Cards	Test consumables that utilize column agglutination technology ("CAT") for our immunohematology instruments sold in the U.S., designed to provide reliable test results and simplify test workflow
BIOVUE Cassettes	Test consumables that utilize CAT for our immunohematology instruments sold outside of the U.S., designed to provide reliable test results and simplify test workflow
Ortho Sera Reagents	Comprehensive immunohematology test menu that we believe covers more than 99% of most tested blood antigens regularly required for transfusion screening globally
Donor Screening	
ORTHO VERSEIA Integrated Processor ("VIP")	Automated pipetting and processing system that combines the ORTHO VERSEIA pipettor and ORTHO Summit Processor to enable end-to-end pipetting and processing for tests used for blood and plasma screening for infectious diseases
Donor Testing Serology	Comprehensive set of infectious disease screens, including important tests for tropical diseases like Chagas that are critical for care in emerging markets

Services and Informatics

In addition to the products we provide, our services and informatics are a critical element of how we deliver value to our customers. As of January 1, 2023, we had approximately 1,000 service teammates globally. We employ highly trained service professionals, including laboratory specialists with advanced qualifications.

Our highly valued suite of ORTHOCARE service offerings includes:

- Guarantee 98% up-time to our e-connected U.S. customers−High instrument reliability and a proactive maintenance program.
- E-CONNECTIVITY Remote Monitoring Software−More than 80% of our installed base of VITROS 5600, XT 7600 and ORTHO VISION platforms are e-connected, enabling remote monitoring and improved analyzer availability.
- Laboratory Informatics−Solutions designed to deliver incremental value to the laboratory, including inventory planning, laboratory productivity metrics and technical documentation.
- ValuMetrix−A highly valued consulting service proven to increase laboratory workflow, productivity and laboratory service levels utilizing lean principles and process excellence. This service offering provides actionable insights into demand for new products, services and workflow.
- Global Technical Solution Center−Seven technical solution centers delivering first-line support in over 15 languages, meaning we can resolve service issues remotely without an on-site visit approximately two-thirds of the time.
- Smart Service Mobile App−First-in-class technology enabled on iPhone and Android devices that allows our service teams to receive up-to-date analyzer health checks, proactive alerts and performance monitoring to help ensure the highest level of reliability is achieved.

- Training and Education−Flexible educational resources for the lifetime of the customer relationship, including virtual technical training, continuing education and professional development.
- Smart Start−Concierge implementation program led by certified project managers. Easier implementation using collaborative software to keep up to date with real-time progress reports, customized dashboards and status updates.
- Merged Reality−Enables product experts to provide remote 'side by side' assistance to field service engineers and customers through mobile devices, including smart glasses. This allows both parties to see the same thing at the same time and provide guided instruction leading to better and faster fix rates.

We also provide our Virena 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.

Digital Solutions and Innovation

We are developing a growing portfolio of digital and data solutions, which we believe improve our customers' clinical and operational outcomes. Our focus is on enabling our customers to deliver smart, connected care across various clinical environments. We strive to turn our instruments into data assets for healthcare providers, labs and policymakers through proprietary and third-party connectivity solutions, such as laboratory information systems and middleware partnerships and connectivity to our information systems. Building on this interoperability, we offer a number of solutions to simplify and automate the testing and instrument management process, including ORTHO Connect, Ortho Plus and Virena. We also plan to develop other digital solutions that turn test results into specific clinical insights and actions via physician or patient facing solutions, such as the QVue mobile application for COVID-19 at-home testing.

Our Strategic Capabilities and Competitive Strengths

There is significant competition in the development and marketing of IVD products, 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, product performance and customer service, 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. There are several global companies with whom we compete, as well as regional and local companies focused on particular markets and/or technologies. Our principal competitors include, among others, Abbott Laboratories, Thermo Fisher Scientific, Danaher, Siemens Healthineers, Diasorin, Bio-Rad, Hologic, Qiagen, bioMérieux and PerkinElmer. Some of these competitors have substantially greater financial, marketing and other resources than we have.

We believe we are well positioned to drive sustained and profitable growth through an ethos of customer-centric decision making and behavior, which informs everything we do from product development to commercial execution. This disciplined focus on serving customers has resulted in, and we believe will continue to create, a business model that can deliver profitable growth and shareholder returns. The cash we generate allows us to reinvest in and reinforce our competitive strengths and strategic capabilities, which then benefit from our global footprint to enable us to be a leader across profitable and high-growth market segments. The competitive strengths that serve as our foundation of success today and can drive future growth include four key aspects, all of which benefit from our talented people and loyal customers:

1. **Superior customer experience and brand loyalty.** Over our more than 80 years supporting the IVD testing needs of our customers, we have developed deep and enduring relationships with our customers. Our ORTHOCARE service program allows us to retain and grow our customer base by providing an industry-leading customer experience driven by quality of service, continuous innovation and access to a diverse product portfolio.
2. **Innovation and research and development ("R&D") capabilities that address unmet needs in new and existing market segments.** We intend to continue to invest in the next generation of instrumentation for each of our business units while keeping abreast of emerging technologies and use-cases, some of which may lead to new business units or revenue streams. Our key strengths include new assay format development, new instrument systems development and the complex integration of the two. In addition, to create new opportunities, manage costs and adapt to a rapidly changing industry, we also enter into strategic partnerships as part of our R&D process.

3. **Operational scale driven by recent investments in U.S. manufacturing capabilities and an extensive and balanced global commercial footprint across more than 130 countries.** We leverage our global footprint of approximately 2,800 commercial sales, service and regional marketing teammates to facilitate successful delivery of innovative solutions to meet our customers' needs in both developed and emerging markets.

4. **Leadership team dedicated to preserving a culture of employee focus and happiness.** We understand that our success relies upon the talent and dedication of our employees. That is why we are committed to attracting, retaining and developing the best talent in the industry. Our culture puts our team members first and prioritizes actions that support happiness, inspiration and engagement. We strive to build meaningful connections with each other as we believe that employee happiness and business success are symbiotic.

Strategy

We are driven to transform diagnostics into action for more people in more places. As we look to the future, we see many opportunities for continued growth. In the short term, our strategy is to invest in R&D to offer a broader test menu to more settings for more patients. Both routine and novel tests are important for leveraging our large and growing installed base of instruments in both laboratories and POC settings. We have also entered the at-home testing market and see opportunities to benefit from additional at-home tests, such as for the flu and RSV.

Additionally, we have made investments to design and develop solutions that are intended to drive laboratory automation and efficiency, improve access to new and novel diagnostics, and enable patients and providers to experience the full benefits of a remote and digitized healthcare system. For example, with the onset of the COVID-19 pandemic, physicians and patients experienced a rapid shift to telemedicine and at-home testing. Going forward, we believe it is important to continue to build digital capabilities and solutions into our offerings to take advantage of this trend and our expectations that it will continue to emerge and evolve.

Longer term, we intend to continue to invest in areas with unmet clinical needs. We are aware of additional markets in which we do not yet compete, but that may benefit from our R&D capabilities and larger operational scale. We also plan to continue to explore the technology and content landscapes for strategic assets. Given the rapid pace of change and deep expertise needed within some of these areas, we expect to leverage third-party partnerships and acquisitions to reduce some of the technical and commercial risks and potentially increase our speed to market with innovative offerings.

As a result of the Combinations, we have increased leverage, cash and optionality. We intend to use a portion of such cash for additional R&D investments. We may also pursue potential business development opportunities, partnerships and acquisitions to support our strategic initiatives. We intend to pursue strategic opportunities that could result in new and relevant technologies and capabilities, or accelerate our commercial growth in attractive end-markets and geographies. We expect to maintain a disciplined approach to inorganic growth.

Current initiatives to execute on this strategy include the following:

- develop and deliver products that represent significant market opportunities, and compete effectively in market segments where service and quality are important;
- focus our R&D efforts;
- leverage our large direct sales team to enhance our cross-selling capabilities across our four business units, and strengthen our relationships with integrated delivery networks, laboratories and hospitals;
- continue to invest in our digital health solutions, including our mobile applications, to expand into new and growing markets; and
- pursue potential acquisitions to support our strategic initiatives.

Research and Development

We continue to focus our R&D efforts on the following areas:

- creation of new and improved products for use on our installed base;
- development of new proprietary product platforms for all of our business units; and
- pursuit of collaboration with other companies for new and existing products and markets.

We balance our R&D efforts against our R&D team's capacity, development timelines and overall cost. Our R&D team is comprised of a balanced mix of experienced professionals with years of experience in the diagnostics industry and recently trained technologists, and together, they have know-how and technical capabilities in key areas, such as biomedical science, information technology ("IT") and engineering. Key strengths of our team include new assay format development, new

instrument systems development and the complex integration of the two. In addition, in order to create new opportunities, manage costs and adapt to a rapidly changing industry, we also plan to enter into strategic partnerships as part of our R&D process.

R&D expenses were $190.5 million for fiscal year 2022, which includes the impact of Ortho's operations from the date of the Combinations. R&D expenses were $95.7 million, and $84.3 million for fiscal years 2021 and 2020, respectively. We anticipate significant investment of our financial resources to product and technology R&D in the foreseeable future.

Sales, Marketing and Distribution

Our current business strategy is designed to serve the continuum of healthcare delivery needs globally, from POC clinicians located in doctor's office practices, to moderately complex POLs, and to highly complex hospitals, laboratories and blood and plasma centers. 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.

Certain of our revenue is driven by a "razor/razor blade" business model. Through this model, we generally sell or place instruments under long-term contracts, which support the ongoing sale of our assays, reagents and consumables. Our instruments are closed systems, requiring customers to purchase the assays, reagents and consumables from us. These sales generate a high proportion of our recurring revenues.

Our sales team is comprised of highly skilled and experienced professionals. We sell products globally and market and distribute products worldwide in a variety of ways, including through a mix of direct, indirect and hybrid distribution strategies. Across our global footprint, we operate a region-specific sales model. Our developed markets, specifically in North America and Western Europe, are served primarily through direct sales; however, we generally utilize a combination of direct sales and third-party distributors in emerging markets, such as China, Asia Pacific, the Middle East, Africa, Eastern Europe and Latin America, as we believe this model is more commercially effective in those regions. Our primary distribution centers are located in North America and Europe.

In North America, we use a generalized sales force for each of our business units other than for donor screening within Transfusion Medicine, which utilizes a separate specialist sales force. 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. This sales force works closely with our key distributors to drive market penetration of our products.

In Europe, our employees support sales and marketing activities in key countries, such as Germany, Italy, France and the U.K. In addition, we have created shared service centers in Galway, Ireland, Prague, Czech Republic and Strasbourg, France to support general and administrative, technical support and customer service functions in Europe.

In the Asia Pacific region, which includes China, Japan and India, our employees support sales and marketing activities, primarily for the Point of Care, Labs and Transfusion Medicine business units. In addition, we have created shared service centers in Shanghai, China and Hyderabad, India to support general and administrative, technical support and customer service functions.

In Latin America, our employees support sales and marketing activities in key countries, such as Brazil and Mexico.

Our global team strives to deliver best-in-class customer service and support by surrounding our customers with devoted and experienced professionals. Our call center team and laboratory specialists serve as the first line of contact for our customers and are available to provide customer training and ongoing customer support. In addition, our network of field engineers is responsible for installing our instruments and providing onsite customer support if necessary.

Our marketing strategy is focused on ensuring that our key product portfolios are supported by clinical validation and health economic and outcomes research that show that our tests deliver fast, high-quality results, are cost-effective to use with lower total cost of ownership, and improve patient outcomes. Our marketing strategy also focuses on effectively marketing to customers a differentiated value proposition and maintaining our brand strength as further discussed above in the section entitled "Our Strategic Capabilities and Competitive Strengths."

We derive a significant portion of our total revenues from a few customers and distributors. Two of our customers, including one of our distributors, which is considered to be among the market leaders, exceeded 10% of our total revenues for fiscal year 2022. In fiscal year 2021, one distributor exceeded 10% of our total revenues. In fiscal year 2020, four of our distributors exceeded 10% of our total revenues. See Note 4 to the Consolidated Financial Statements.

Manufacturing

Our manufacturing operations benefit from our broad global footprint, scale and workforce capabilities. We believe our plant capacity and available space are sufficient to accommodate growth, maintain quality and help ensure continuity. Our primary manufacturing facilities are located in San Diego, California, Carlsbad, California, Athens, Ohio, Raritan, New Jersey, Rochester, New York, Pompano Beach, Florida, Pencoed, Wales and Galway, Ireland.

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 or immunochemistry, and production areas 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 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 some are also supplied to Beckman 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 ISO 13485:2016 and MDSAP medical device standards. Most of the products are packaged and subsequently distributed by our San Diego distribution center.

Our Athens, Ohio facility consists of a variety of clean room and chemistry laboratories and customized reagent filling and packaging areas to support the manufacturing at the facility of all products under current good manufacturing practices ("cGMPs"). This facility supports 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 (ELISA). 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 Raritan, New Jersey facility manufactures our in vitro diagnostic donor screening and immunohematology products that are distributed globally. Manufacturing processes consist of formulation, filtration, filling, labeling, chemistry analysis, serological and microbial testing, as well as packaging. The product filling process occurs in a microbially controlled filling area using highly automated equipment and systems. This facility is a CBER licensed biologics/510(k) facility, certified to ISO 13485 and MDSAP medical device standards, ISO14001:2015, Environmental Management System, and the OSHA Voluntary Protection Program ("VPP") Star Site. This facility is recognized for environmental stewardship by the New Jersey Department of Environmental Protection. Warehousing, direct shipping and shipping logistics with cold chain storage capability are handled at this facility with products transported to our distribution facilities for onward handling to end customers.

Our Rochester, New York facility consists of three sites for slide manufacturing, fluid manufacturing and CNP equipment manufacturing. This facility manufactures the slides and fluids used for clinical diagnostic assays run on our VITROS analyzers. Manufacturing capabilities include formulation, lyophilization, filling, coating, slitting, custom featuring, assembly and packaging, all under cGMPs. This facility is certified to ISO 13485:2016 and MDSAP medical device standards and ISO 14001 and is part of the OSHA VPP program for safety. Warehousing and shipping logistics with cold chain storage capability are handled at this facility with products transported to our distribution facilities for onward handling to end customers.

Our Pompano Beach, Florida facility manufactures our immunohematology CAT products that are distributed to the North American market, encompassing the U.S., Canada and Puerto Rico. The manufacturing processes include subassembly activities required for reagent formulation, product filling, chemistry analysis, serological testing and product packaging. The product filling process occurs in a microbially controlled filling area using highly automated, state-of-the-art equipment and systems. This facility is a CBER licensed biologics/510(k) facility, certified to ISO 13485 and MDSAP medical device standards, ISO 14001 and ISO 45001. Warehousing and shipping logistics with cold chain storage capability are handled at this facility with products transported to our distribution facilities for onward handling to end customers.

Our Pencoed, Wales facility manufactures certain of our immunoassay and immunohematology products that are distributed globally. The immunoassay manufacturing processes include conjugation, purification, biological formulation, lyophilization, dispensing, testing and packaging. The processes are highly automated with state-of-the-art systems and key processes are executed in an environmentally controlled area. By utilizing electronic batch records, each product is manufactured with high quality and consistency. This facility is certified to ISO 13485 and MDSAP medical device standards, ISO 14001 and ISO

45001. Warehousing and shipping logistics with cold chain storage capability are handled at this facility with products transported to our distribution facilities for onward handling to end customers.

Our Galway, Ireland facility manufactures in vitro diagnostic test kits. This facility also provides sales and technical support and warehouses and distributes products from many of our manufacturing locations into the EMEA markets. This facility operates under and is certified to ISO 13485:2016.

We seek to conduct our manufacturing in compliance with QMS regulatory requirements of the U.S., 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 other international and local public health and regulatory agencies.

Suppliers and Raw Materials

We obtain raw materials from reputable outside suppliers and believe our business relationships with them are good. Some of our raw materials are available from a limited number of sources. During 2022, we encountered some increasing pressures on raw material pricing. To help mitigate these supply chain challenges, we are (i) partnering with suppliers to invest in additional capacity and raw material inventory, (ii) diversifying our supply base, where possible, to minimize reliance on a single source of supply for key raw materials and components and (iii) creating redundancy in our global supply chain. In addition, we routinely evaluate our supply chain for potential gaps and continue to take other steps intended to help address continuity. For more information related to our supply chain, see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Impact of the COVID-19 Pandemic—Supply Chains," Part I, Item 1A, "Risk Factors—Risks Relating to Our Business, Strategy and Operations—The COVID-19 global pandemic has adversely affected, and may continue to adversely affect, our business operations, strategy, financial performance and results of operations, the extent of which is uncertain and difficult to predict" and Part I, Item 1A, "Risk Factors—Risks Relating to Our Business, Strategy and Operations—Interruptions and delays in the supply of raw materials, components, equipment and other products and services could adversely affect our operations and financial results."

Collaboration Arrangements

We have various collaboration arrangements, which provide us with the rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. These arrangements are often entered into in order to share risks and rewards related to a specific program or product. Our collaborative arrangements include a number of ongoing relationships for test development, instrument development and automation track design and distribution.

In connection with the Combinations, we acquired the ongoing collaboration arrangement (the "Joint Business") between Ortho and Grifols Diagnostic Solutions, Inc. ("Grifols"), under which Ortho and Grifols agreed to pursue a collaboration relating to Ortho's Hepatitis and HIV diagnostics business. The arrangement is governed by an agreement (as amended, the "Grifols Agreement") originally entered into in 1989 with a 50-year term, which, among other things, provides for a profit sharing arrangement whereby, the profits we generate from our production and sale of Hepatitis and HIV diagnostics products are shared with Grifols, and the profits generated by Grifols from its sale of certain antigens and licensing of certain intellectual property rights are shared with us. The Grifols Agreement also gives us the right to use such intellectual property. The majority of the patents underlying these intellectual property rights have expired. Grifols also supplies us with a portion of the antigens used in its production of these diagnostics products.

Today, the most significant benefit to us under the Grifols Agreement is the manufacture and sale by us of HIV and Hepatitis tests, which are solely performed by us. During the fiscal year ended January 1, 2023, the revenue associated with the use of this patented intellectual property was less than 1% of our total revenues and the expense associated with the antigens supplied to us by Grifols was less than 2% of our cost of goods sold.

The initial 50-year term of the Grifols Agreement will expire on December 31, 2039, at which time it will automatically renew for successive five-year periods unless either party has notified the other at least five years in advance of such date that it wishes to terminate the Grifols Agreement. Notwithstanding the initial term, in Europe, the Grifols Agreement will terminate on a country-by-country basis upon the expiration of the last patent right with respect to such country, provided that either party has a right to extend the Grifols Agreement for successive one-year terms by giving the other party notice prior to the termination date. To date, the parties have extended the Grifols Agreement for Europe on an annual basis. The Grifols Agreement may also be terminated by the non-breaching party if there is a breach or default of the agreement which is not cured during a 60-day cure period.

Seasonality

Sales of our respiratory products are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons, typically prevalent during the fall and winter. Historically, sales of our influenza products have varied from year to year in

volume and timing based, in large part, on the severity, length and timing of the onset of the cold and flu season. In addition, the SARS-CoV-2 virus may have similar seasonal demands and impacts on our revenues in the future.

Government Regulations

U.S. Regulations of Medical Devices

The testing, manufacture and commercialization of the majority of our diagnostics products and analyzers in the U.S. are subject to regulation by numerous governmental authorities, principally the FDA as medical devices and corresponding state regulatory agencies. Pursuant to the U.S. Federal Food, Drug, and Cosmetic Act (the "FDCA") and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices.

In the U.S., medical devices are classified into one of three classes (Class I, II or III) depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I devices are those with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of cGMPs for medical devices known as the Quality System Regulation ("QSR") facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device, like performance standards, post-market surveillance, patient registries and FDA guidance documents. Class III devices generally pose the highest risks, such as life sustaining, life supporting or some implantable devices, and are typically subject to premarket approval to ensure their safety and effectiveness. Our current products are all Class I or II.

While most Class I devices are exempt from the premarket notification requirement under Section 510(k) of the FDCA ("510(k)"), manufacturers of most Class II devices are required to submit to the FDA a premarket notification under 510(k) requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance, which can be a lengthy, expensive and uncertain process. 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 ("PMA") 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. Class III devices require approval of a PMA application evidencing safety and effectiveness of the device. We currently market the majority of our diagnostic products in the U.S. pursuant to 510(k) clearances and PMA approvals.

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 ("EUA"), for certain emergency circumstances after the Secretary of the U.S. Department of Health and Human Services ("HHS") 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 cGMPs requirements to accommodate emergency response needs. Products subject to an EUA must still comply with the conditions of the EUA, including labeling and marketing requirements. Moreover, the authorization to market products under an EUA is limited to the period of time the public health emergency declaration is in effect as determined by HHS. On February 4, 2020, the HHS Secretary determined that the novel coronavirus presented a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19. All of our current products for testing for the COVID-19 virus are sold in the U.S. under EUA.

The FDA's Clinical Laboratory Improvement Amendment of 1988 ("CLIA") regulates 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 QSR 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.

U.S. Regulation of Biological Products

Certain of our blood screening products are regulated by the FDA as biological products, also called biologics. In the U.S., biologics are subject to regulation under the FDCA and the Public Health Service Act ("PHSA"), and other federal, state, local and foreign statutes and regulations. The process required by the FDA before biologics may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements;
- submission to the FDA of an Investigational New Drug application ("IND") which must become effective before human clinical trials may begin. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans;
- approval by an Institutional Review Board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application ("BLA") after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is to be produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced and of select clinical trial sites, the FDA may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Any biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic

reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

FDA Enforcement

The FDA may withdraw a marketing authorization if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things: restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, product recalls, fines, warning letters, untitled letters, clinical holds on clinical studies, refusal of the FDA to approve pending applications or supplements to approved applications, product seizures or detention, refusal to permit the import or export of products, consent decrees, corporate integrity agreements, the issuance of corrective information, injunctions, or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of biologics and medical devices. A company can make only those claims relating to safety and efficacy, purity and potency that are cleared or approved by the FDA and in accordance with the provisions of the authorized label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Regulations Outside of the U.S.

For marketing outside the U.S., we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the U.S., and may require us to perform additional or different preclinical or clinical testing regardless of whether we have obtained FDA clearance or approval. The amount of time required to obtain necessary approvals 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 U.S. is typically in the European Union ("EU"), Australia, Brazil, Canada, China, Japan and the U.K. EU regulations and directives generally classify healthcare products either as medicinal products, medical devices or IVD. In order for medical devices to be placed on the European market or put into service, they must bear a CE marking. The CE marking may only be affixed if the product meets the essential safety and performance requirements. Manufacturers must establish a specific quality management system that ensures that a risk management procedure and a clinical evaluation are carried out for each device. The conformity assessment usually involves an audit of the manufacturer's quality system by a notified body accredited by an EU member state and, depending on the type of device, a review of the technical file from the manufacturer on the safety and performance of the device. In some other cases, the notified body must seek a scientific opinion from specific expert panels or the European Medical Agency before issuing a CE certificate.

In addition, the EU has adopted the EU Medical Device Regulation (EU 2017/745) (the "EU MDR") and the In Vitro Diagnostic Regulation (EU 2017/746) (the "EU IVDR"), each of which impose stricter requirements for the marketing and sale of medical devices than in the U.S., including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The compliance deadlines for the EU MDR and EU IVDR were May 2021 and May 2022, respectively. The transition period provided for in the EU MDR for existing certifications issued under the previous Medical Devices Directive will end on May 26, 2024. The EU IVDR has been applicable since May 26, 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from May 26, 2025 for high risk in vitro diagnostics to May 26, 2027 for lower risk in vitro diagnostics, and to May 26, 2028 for certain provisions concerning devices manufactured and used in health institutions (Regulation (EU) 2022/112). However, the transition periods might still be subject to change.

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), including NMPA's Announcement (No. 104, 2020), which provides an accelerated pathway for the localization of imported medical devices and IVD products in China by permitting (for certain classes or products) the same medical approval license previously approved by the mainland authorities to apply to provincial domestic enterprises in China, providing for the same product design and equivalent quality system that is traceable to the imported licensed product. 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 the U.K., approvals must be obtained from the U.K.'s Medicine and Healthcare Products Regulatory Agency. 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 U.S., the MDSAP is a single regulatory audit of our QMS that satisfies the requirements of all five of these jurisdictions.

Other Healthcare Laws

Our products are subject to various healthcare-related laws regulating fraud and abuse, R&D, pricing, sales and marketing practices, and the privacy and security of health information. 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. Specific health-care laws and regulations that we are subject to include:

- the federal Physician Self-Referral Law, which prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, and prohibits the entity from presenting or causing to be presented claims to Medicare for those referred services;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, where one purpose is to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of medical device manufacturers;
- the federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters.
- the federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers, including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices, and regulates device marketing;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities that potentially harm customers; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to item or services reimbursed by any third-party payor, including commercial insurers; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures and state laws related to insurance fraud in the case of claims involving private insurers.

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. Specific data privacy and security laws that we are subject to include:

- HIPAA, which imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA;
- the California Consumer Privacy Act of 2018 ("CCPA"), which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. Further, the California Privacy Rights Act, which amends the CCPA, became operative on January 1, 2023 and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for certain higher risk data processing, and opt outs for certain transfers of personal information and uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations, which are in the process of finalization, and could result in increased privacy and information security enforcement. A similar law in Virginia also took effect January 1, 2023, and similar laws also have passed in other states, including Colorado, Utah, and Connecticut. Comprehensive privacy laws also have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the U.S.;
- the FTC Act, and state consumer protection laws, enforced by many state Attorneys General for online collection, use, dissemination and security practices that appear to be unfair or deceptive;
- outside the U.S., the General Data Protection Regulation 2016/679 (the "GDPR") and the U.K. data protection regime consisting primarily of the U.K. General Data Protection Regulation and the U.K. Data Protection Act 2018 (collectively, the "U.K. GDPR"), which govern the processing of information in those jurisdictions, and could result in significant fines (up to the greater of €20 million / £17.5 million or 4% of total annual revenue), regulatory investigations, reputational damage, orders to cease or change our processing of our data, enforcement notices or assessment notices (for a compulsory audit), civil claims including representative actions and other class action type litigation;
- E.U. and U.K. rules with respect to cross-border transfers of personal data out of the European Economic Area (the "EEA") and the U.K., respectively, which are in flux, including in light of a decision by the Court of Justice of the E.U. invalidating the E.U.-U.S. Privacy Shield Framework, and the European Commission's recent publishing of revised standard contractual clauses, which we must now consider and apply, where applicable. In light of these changing requirements, we could suffer additional costs, complaints, regulatory investigations or fines, and if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services and the geographical location or segregation of our relevant systems and operations, which could adversely affect our financial results, including because we rely on third parties in other countries;
- evolving privacy laws on cookies and e-marketing. In the E.U., regulators are increasingly focusing on compliance with requirements in the online behavioral advertising ecosystem, and current national laws that implement the ePrivacy Directive will be replaced by an E.U. regulation known as the ePrivacy Regulation which will significantly increase fines for non-compliance. While the text of the ePrivacy Regulation is still under development, a recent European court decision and regulators' recent guidance are driving increased attention to cookies and tracking technologies. In the U.S., the FTC and many state laws have increasingly focused on the collection and use of behavioral data, including geolocation and biometric information. As regulators start to enforce a stricter approach, this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, increase costs and subject us to additional liabilities;
- China's multiple pieces of legislation governing the healthcare industry involve prescribing complex regulatory requirements governing different types of data across a continuum of care, and various supervisory authorities frequently conduct inspections and investigations. These include:

- China's Cybersecurity Law, including data localization requirements that require operators of critical information infrastructure ("CIIOs") to store personal information and important data collected and generated from the critical information infrastructure within China. Failure to do so can result in fines of up to RMB 100,000 for the relevant entity as well as for the personnel directly responsible;
- China's Data Security Law ("Data Security Law"), which became effective on September 1, 2021, and applies extraterritorially and to a broad range of activities that involve "data" (not only personal or sensitive data). Under the Data Security Law, entities and individuals carrying out data activities must abide by various data security obligations, including implementing the appropriate level of protective measures for each respective class of data and storing data locally in China (or in compliance with certain data transfer restrictions);
- China's Personal Information Protection Law ("PIPL"), which is similar to the GDPR and also applies extraterritorially. The PIPL provides the legality of personal information processing and the basic requirements of notice and consent, sets out data localization requirements for CIIOs and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities, and provides a list of rules for transferring personal information outside of China. Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities, among other fines and criminal liabilities, including ones that can be placed on responsible personnel; and
- several regulations and draft regulations for public comments, promulgated by the People's Republic of China, which are designed to provide further supplemental guidance in accordance with the laws mentioned above;

- self-regulatory standards that privacy advocacy groups, the technology industry and other industries have established or may establish and 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 other 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; and
- enacted or considered legislation similar to the above in other countries around the world, in which we do business.

Environmental, Health and Safety Laws

We are subject to various environmental, health and safety laws and regulations both within and outside the U.S., 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.

Laws Governing Reimbursement Activities

Healthcare providers that purchase medical devices generally rely on third-party payors, including the Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. Reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes as well as budgetary pressures in the U.S. and globally. For example, in the U.S.:

- the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA") implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;

- the Budget Control Act of 2011 reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken;

- the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), enacted in 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual

updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations; and

- certain provisions of the Protecting Access to Medicare Act of 2014 ("PAMA") were implemented by CMS in 2018, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, the revised Medicare reimbursement rates were scheduled to apply to clinical diagnostic laboratory tests furnished on or after January 1, 2018. The revised reimbursement methodology is expected to generally result in relatively lower reimbursement under Medicare for clinical diagnostic lab tests than has been historically available. Any reduction to payment rates resulting from the new methodology is limited to 10% per test per year in 2018 through 2020, and to 15% per test per year in 2021 through 2023.

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

We are subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act of 2010 (the "Bribery Act"), the Brazilian Anti-Bribery Act (also known as the Brazilian Clean Company 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 U.S. 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 and certain environmental, social and governance ("ESG") requirements applicable to our government contracts, and failure to address these laws and regulations, ESG requirements, or to comply with government contracts could result in fines, debarment or exclusion from federal healthcare or global tender programs, or harm our business by a reduction in revenue associated with these customers. We are also subject to audits 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, tradenames and processes. In the aggregate, our intellectual property is of material importance in the operation of our business. However, although we possess numerous patents, trade secrets and trademarks that are important to our business, we believe that no single patent, trade secret or trademark by itself is material to our business as a whole.

We actively pursue patents for technologies that are considered patentable. We have issued patents in the U.S. and internationally, and have patent applications pending throughout the world. However, important factors, many of which are not within our control, can affect whether and to what extent patent protection in the U.S. and in other important markets worldwide is obtained. 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.

It has been our policy to file for patent protection in the U.S. and other countries with significant markets for our products, 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 royalties (some of which may be significant) in order to exploit certain of our product strategies. Moreover, licenses to such patents may not be available to us at all or 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 technologies. We have entered into agreements with third parties to license and use their intellectual property, although no one such license is material to our business as a whole. 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.

In addition to seeking patent protection where appropriate, we also protect some of our intellectual property as trade secrets. We seek to protect our trade secrets and proprietary technologies in many ways, including by entering into confidentiality agreements with employees and third parties with which we do business (such as potential licensees, customers, vendors, strategic partners and consultants). In addition, we have implemented certain security measures in our laboratories and offices to protect the confidential and proprietary nature of these technologies.

In addition to patent and trade secret protection, we have also registered or applied to register certain trademarks and service marks in the U.S. 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 "Business Units and Products."

Under many of our contractual agreements that involve the sale of our products, 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 our products sold under those agreements.

Human Capital and ESG Strategies

Human Capital Resources

As of January 1, 2023, we had approximately 7,000 employees worldwide, with approximately 4,200 employees in the U.S. and approximately 2,800 employees outside of the U.S. We employ approximately 1,700 manufacturing employees and approximately 2,800 employees in commercial sales, service and regional marketing positions worldwide, including approximately 1,000 service teammates. Approximately 15% of our associates globally are covered by a union, collective bargaining agreement or works council, including associates in Austria, Belgium, Brazil, France, Germany, Italy, Spain, Sweden and the U.K. To date, we have experienced no work stoppages and believe that our employee relations are good.

Diversity, Equity 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 depend in large part on our ability to attract, retain, develop and motivate 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 fostering a culture that supports diverse talents, experiences and perspectives and an environment of mutual respect, equity and collaboration that helps drive our business. As a global organization, our unique perspectives, diverse backgrounds and collective strengths drive creative solutions, breakthrough innovation and highly productive teams.

In September 2022, we invited all of our employees to participate in a confidential, global survey to gather feedback and gain insights on key cultural and engagement factors. Nearly 75% of global employees participated in the survey, and results show positive sentiment around engagement and workplace culture. Respondents indicated a strong alignment to our strategic priorities and found meaning and purpose in their work. We believe we are stronger together and will prioritize actions that support happy, inspired and engaged team members. We plan to conduct periodic pulse surveys with employees throughout 2023 to measure progress and focus on continuous improvement.

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 keeping with our core values, we are steadfast in taking action to provide equal employment opportunity in accordance with all applicable federal, state and local laws.

In addition, we review Company programs, policies, procedures and activities with diversity and inclusion in mind. We have established newly defined core behaviors based on the QuidelOrtho Way, which define our core values as a company and our ways of working together. These core behaviors include "bring your best," which reflects each individual contributing to their highest potential, "embrace inclusion," which reinforces the role each team member plays in creating a diverse, equitable and inclusive work environment, and "commit to service," which reflects our value of serving our customers and communities in the core of everything we do. We plan to expand upon the foundation of diversity and inclusion by incorporating other inclusive behaviors into these core behaviors and providing training to support all of our employees in being authentic in their self-expression and open to the self-expression of others.

As of January 1, 2023, 43% of our U.S. employees identified as female and 39% of our U.S. employees identified as having a racial and ethnic background other than white. As of January 1, 2023, our executive management team consisted of 8 members, of whom 25% identified as female. In addition, as of January 1, 2023, our board of directors (the "Board") consisted of 12 members, of whom 25% identified as female and 17% identified as having a racial and ethnic background other than white.

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 to align with our strategic and stockholders' interests. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, equity compensation awards and other employee benefits. 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, which vary by country, and may include 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.

Health, Safety and Environmental

Our operations and facilities are subject to various laws and regulations domestically and around the world governing the protection of the environment and health and safety, including the discharge and emissions of pollutants to air and water and the handling, management and disposal of hazardous substances. We are committed to employee health and safety in the workplace. In the U.S., our manufacturing facilities hold various certifications depending on the site. We also 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.

We believe that all of our manufacturing and distribution facilities are operated in compliance with existing environmental requirements in all material respects, including the operating permits required thereunder. Although we do not currently expect the costs of compliance with existing environmental requirements to have a material impact on our financial position, we may incur additional costs or obligations to comply with environmental and health and safety requirements as a result of changes in law or customer demands, including those related to our products. In addition, many of our manufacturing sites have a long history of industrial operations, and remediation is or may be required at a number of these locations. Although we do not currently expect outstanding remediation obligations to have a material impact on our financial position, the ultimate cost of remediation is subject to a number of variables and is difficult to accurately predict.

Corporate Philanthropy

We listen to our internal and external stakeholders and aim to translate their needs into innovative solutions, in the products we offer and in our corporate philanthropy work. Our charitable giving programs operate under the QuidelOrtho Community Action Review and Endowment Squad ("QCARES") committee, which is responsible for quarterly review and approval of charitable contributions proposed by employees. Our charitable giving programs and activities in the U.S. 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.

ESG Strategy

As a world leader of in vitro diagnostics, we develop and manufacture innovative diagnostic technologies and solutions that transform data into answers and understanding into actions to enhance clinical outcomes for more people in more places every day. We bring fast, accurate and reliable diagnostics when and where they are needed most – from home to hospital, lab to clinic.

As part of our ESG strategy, we are focused on the following cornerstones:

- monitoring the impacts of waste generation and energy and water usage consumption;
- implementing efficiencies at our global facilities and in our product manufacturing that mitigate risks, reduce costs and address impacts;

- supporting equitable access to healthcare in our communities;
- fostering a culture of happy people that welcomes and promotes diversity and inclusion;
- advancing good corporate governance that aids our long-term business success; and
- being accountable, fair and transparent.

We believe these cornerstones contribute to the value created by our Company for all of its stakeholders and to fulfilling their expectations.

Information Available on Our Website

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.quidelortho.com, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (the "SEC"). From time to time, we may use our website as a channel of distribution of material information related to the Company. Financial and other material information regarding the Company is routinely posted on and accessible at https://ir.quidelortho.com/. The information contained on or connected to our website is not deemed to be incorporated by reference into this Annual Report or filed with or furnished to the SEC and should not be considered part of this Annual Report.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. The risks and uncertainties described below are not the only risks and uncertainties that we face. Additional risks and uncertainties not known to us or that we currently deem immaterial may also impair our business operations. The occurrence of any of the following risks may materially and adversely affect our business, financial condition, results of operations and future prospects.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, results of operations and financial condition:

- risks related to the consummation of the Combinations, including (i) failure to integrate successfully the businesses of Quidel and Ortho in the expected timeframe, or at all; (ii) the synergies attributable to the Combinations may vary from expectations; (iii) continued incurrence of significant transaction and merger-related costs; (iv) disruption of our business relationships; and (v) business issues of Quidel or Ortho prior to the Combinations being imputed to the other;
- outbreaks of contagious diseases and other adverse public health developments, such as the COVID-19 global pandemic;
- the highly competitive nature of our industry and market segment;
- failure to research and successfully develop new technologies, products and services and develop new markets;
- adverse developments in global market, macroeconomic and geopolitical conditions;
- fluctuations or a decline in sales of our COVID-19 and influenza diagnostics tests;
- the loss of any key distributor or the failure to retain or expand our customer relationships;
- interruptions and delays in the supply of raw materials, components, equipment and other products and services provided to us, and manufacturing or warehousing problems or delays;
- the failure of our collaboration partners to fulfill their obligations to us;
- our inability to meet demand for our products and services;
- decreases in the number of surgical procedures performed, and the resulting decrease in blood demand;
- fluctuations in our cash flows as a result of our reagent rental model;
- our inability to achieve market acceptance of our products;
- significant changes in the healthcare industry and related industries that we serve, in an effort to reduce costs;
- consolidation of our customer base and the formation of group purchasing organizations;
- inability to realize the anticipated benefits of acquisitions and divestitures;
- the occurrence of natural disasters, public health crises, geopolitical crises and other catastrophic events that may adversely affect our results of operations;
- risks associated with our non-U.S. operations and international sales, including currency translation risks, the impact of possible new tariffs, trade embargoes or trade wars and compliance with applicable trade measures;
- our inability to protect our information systems from cyber-based attacks, security breaches or privacy violations and failure to protect our cloud-based solutions;
- our inability to develop, obtain and protect our proprietary technology rights or defend against intellectual property infringement suits against us by third parties;
- the loss of EUA by the FDA on our COVID-19 products;
- our inability to obtain or maintain required clearances or approvals for our products, including approval requirements of the foreign countries in which we sell our products;
- our ability to adequately manage our clinical studies;
- failure to comply with applicable regulations, which may result in significant costs or the suspension or withdrawal of previously obtained clearances or approvals;
- disruptions at government agencies that prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner;
- inability to procure government contracts, including due to government-sponsored tendering requirements, lack of funding and compliance and possible sanctions risks associated with our contracts with government entities;
- liability claims and harm to our reputation resulting from claims that our products are defective;

- failure to comply with laws and regulations, including healthcare regulations, laws and regulations associated with our use of hazardous materials, anti-corruption laws and regulations, and federal, state and foreign data protection laws and regulations;
- risks related to changes in U.S. and foreign income tax laws and regulations;
- changes in our tax rates or exposure to additional income tax liabilities or assessments;
- need to raise additional funds to finance our future capital or operating needs or other business purposes;
- risks related to our indebtedness, which as of January 1, 2023, includes indebtedness of $2,638.3 million, as well as remaining availability under our Revolving Credit Facility (as defined in this Annual Report) of $786.9 million (net of $13.1 million of outstanding letters of credit);
- our ability to generate cash flow to service our debt obligations;
- restrictions imposed under the agreements governing our indebtedness from time to time, which may limit our operating flexibility;
- difficulty attracting, motivating and retaining executives and other key employees;
- unexpected payments to any pension plans applicable to our employees;
- work stoppages, union negotiations, labor disputes and other matters associated with our labor force;
- the outcomes of legal proceedings instituted against us;
- risks that the insurance we maintain may not fully cover any or all potential exposures;
- certain provisions of our amended and restated certificate of incorporation (our "Charter"), Delaware law and our amended and restated bylaws (our "Bylaws") that may make takeover attempts difficult, which could depress the price of our common stock, or limit our stockholders' ability to obtain a favorable judicial forum for disputes;
- additional costs and new risks associated with ESG matters;
- the volatility of the market price of our common stock;
- risks associated with future sales of our common stock by us or our stockholders in the public market; and
- failure to develop or maintain an effective system of internal controls.

The following is a more complete discussion of the risks facing our business that we have determined are currently material.

Risks Relating to the Consummation of the Combinations

The failure to integrate successfully the businesses of Quidel and Ortho in the expected timeframe, or at all, would adversely affect our future business and financial performance.

The combination of two previously independent companies, Quidel and Ortho, is a complex, costly and time-consuming process. As a result of the Combinations, we will be required to devote significant management attention and resources to integrate the business practices and operations of Quidel and Ortho. The integration process may disrupt the business of either or both of Quidel and Ortho and, if implemented ineffectively, could preclude realization of the full benefits, or any benefits, we expect to result from the Combinations. Any failure to meet the challenges involved in successfully integrating the operations of Quidel and Ortho or otherwise to realize the anticipated benefits of the Combinations could also seriously harm our results of operations. In addition, the overall integration of Quidel and Ortho may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of or harm to customer or other partner relationships and diversion of management's attention, and may cause our stock price to decline. The difficulties of combining the operations of Quidel and Ortho include, among others:

- managing a significantly larger company and expanded business, which will pose substantial challenges for management, including challenges related to the management and monitoring of the current and expanded operations and associated increased costs and complexity;
- coordinating geographically separate organizations, including extensive international operations;
- the potential diversion of management's focus and resources from other strategic opportunities and from operational matters;
- performance shortfalls as a result of the diversion of management's attention;
- aligning and executing our strategy;
- the disruption of relationships with, or the loss of customers, potential customers and other business partners and potential business partners;
- maintaining employee morale and retaining and attracting key management and other employees;

- the disruption of, or the loss of momentum in, Quidel's and Ortho's ongoing business or inconsistencies in standards, controls, systems, procedures and policies;
- integrating two unique business cultures;
- the possibility of faulty assumptions underlying expectations regarding the integration process and results;
- consolidating corporate and administrative infrastructures and addressing duplicative operations;
- coordinating sales, distribution and marketing efforts;
- integrating IT, communications and other systems;
- changes in applicable laws and regulations and addressing multiple laws and regulations across the globe;
- managing tax costs or inefficiencies associated with integrating the operations of Quidel and Ortho;
- unforeseen expenses associated with the Combinations; and
- taking actions that may be required in connection with obtaining regulatory approvals.

Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations. In addition, even if the operations of Quidel and Ortho are integrated successfully, we may not realize the full benefits of the Combinations, including the synergies, cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated timeframe, or at all.

The synergies attributable to the Combinations may vary from expectations.

We may fail to realize the anticipated benefits and synergies expected from the Combinations, which could adversely affect our business, financial condition and operating results. The success of the Combinations will depend, in significant part, on our ability to successfully integrate the businesses of Quidel and Ortho and realize the anticipated strategic benefits and synergies from the Combinations. We believe that the combination of the businesses of Quidel and Ortho will complement each party's strategy by providing a balanced and diversified product portfolio, operational efficiencies, supply chain optimization, complementary geographic footprints, product development synergies and cash flow and margin enhancement opportunities. However, achieving these goals requires, among other things, successful integration and realization of the targeted cost synergies expected from the Combinations. The successful integration and anticipated benefits of the Combinations and actual operating, technological, strategic and revenue opportunities may not be realized fully or at all, or may take longer to realize than expected. If we are unable to achieve these objectives and realize the anticipated benefits and synergies expected from the Combinations within the anticipated timeframe or at all, our business, financial condition and operating results may be adversely affected.

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

We have incurred and expect to continue 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, retention and other employment-related costs, including payments that may be made to certain of our executives, filing fees, travel expenses and other related charges. There are also processes, policies, procedures, operations, technologies and systems that must be integrated in connection with the Combinations and the integration of Quidel's and Ortho's businesses. While we have assumed that a certain level of expenses would be incurred in connection with the Combinations 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.

In addition, there may be additional unanticipated significant costs and expenses in connection with the Combinations. Although we expect that the strategic benefits of the Combinations will offset the transaction expenses and implementation costs over time, this net benefit may not be achieved in the near term or at all.

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. 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 terminating their business relationships with us. These disruptions could have an adverse effect on our business, financial condition, results of operations or prospects, including an adverse effect on our ability to realize the anticipated benefits of the Combinations.

Business issues faced by Quidel or Ortho prior to the Combinations may be imputed to the operations of the other.

To the extent either Quidel or Ortho had, or was perceived by customers to have, operational challenges, such as product availability, product or service performance, quality, workforce or other issues, those challenges may raise concerns by existing customers of the other company, which may limit or impede our future ability to obtain additional business from those customers.

Risks Relating to Our Business, Strategy and Operations

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

Any significant outbreak of contagious diseases and other adverse public health developments in countries where we operate could have a material and adverse effect on our business, financial condition and results of operations. 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 have been affected in a number of ways and may be further adversely impacted in a number of ways, including, but not limited to, the following:

- increased costs in our manufacturing, production and shipping processes;
- a slowdown or stoppage in the supply chain of our raw materials, components, including but not limited to the key components of our instruments and assays, 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;
- 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 customers that could result in reductions in demand for routine, elective and other non-COVID-19 related healthcare procedures and testing;
- disruptions to our operations, sales, distribution, R&D and other important business activities and those of our business partners, including a shutdown of one or more of our facilities, warehouses or product lines;
- our ability to meet any increased demand for our COVID-19 testing products;
- limitations on employee resources and availability, including due to sickness or personal quarantine;
- disruptions encountered by health regulatory agencies globally in their operations. For example, the FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced, and as a result, review and approval of product registrations may be materially delayed;
- an adverse impact on collections and timing of cash receipts from our customers, which could result in significant fluctuations in our cash flows from period to period; and
- an increase in the volatility of our stock price, fluctuations in foreign currency exchange rates or rising interest rates.

In response to increased demand of some of our products brought on by COVID-19, we rapidly and significantly expanded 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 decreases in demand for our products, 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, excess capacity and the value of those investments being written down or written off. Similarly, we have experienced significant volatility in demand for our COVID-19 products since they launched, with periods of significant demand and periods where we experienced dramatic decreases in demand. Demand has fluctuated as a result of various factors, including the resurgences of COVID-19 and its variants, the supply of COVID-19 tests generally, the purchasing activity of government entities, and the dissemination and effectiveness of vaccinations. As the COVID-19 pandemic reaches an endemic stage, the extent to which it may continue to impact demand for our products depends on these and future developments, which are highly uncertain and difficult to predict.

The COVID-19 pandemic has also resulted in global supply chain challenges. For instance, we have experienced shortages and delays in receiving certain raw materials and other components for our products and have experienced logistics and distribution

challenges, as well as challenges in labor availability and rising labor costs, all of which have affected our ability to fulfill customer orders, including instrument placements, on a timely basis. Supply chain, production, logistics and distribution challenges have impacted, and we expect will continue for some period of time to impact, our results of operations. Although we and our contract manufacturer partners, suppliers of raw materials and other third-party vendors are pursuing additional sources for certain of these components, we may be unable to identify additional suppliers. We have also encountered and may continue to encounter increases in idle facility costs and freight and distribution costs, which in some instances have affected the pricing of our products. Any prolonged and significant supply chain disruptions or inability to provide products in countries adversely impacted by the COVID-19 pandemic could impact our revenues, increase our costs and negatively affect our business relationships and reputation, as well as our operating results.

The effects of COVID-19 may exacerbate the impact of other risks described in this Annual Report. As the COVID-19 pandemic reaches an endemic state, the degree to which it continues to impact our business operations, strategy, financial condition and results of operations will depend on future developments that are uncertain and difficult to predict. Although COVID-19 infection rates and severity have decreased recently, the occurrence, spread, severity and duration of any new outbreaks or resurgences, including the emergence and spread of new variants of COVID-19, actions taken to contain the resurgences or variants, and economic repercussions of the virus remain uncertain. We continue to evaluate the nature and extent to which COVID-19 may impact our business and operations.

The industry and market segment in which we operate are highly competitive, and our failure to compete effectively could adversely affect our sales and results of operations.

Our diagnostic tests and services compete with similar products made by our competitors. We may not be able to supply customers with products and services that they deem superior or at competitive prices, and we may lose business to our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diagnostics companies and diagnostic divisions of diversified healthcare companies and conglomerates. We also face competition from our distributors and retail customers 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, managerial, technical, R&D, clinical, manufacturing, and regulatory resources, capabilities and experience, and larger, more established marketing, sales, distribution and service organizations and other resources 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:

- customers and potential customers believe our competitors' products and services better address their needs and expectations through product performance, product offerings, cost, automation or work-flow efficiencies, and even if we can demonstrate that our products meet their needs and expectations, they may resist changing to our products;
- our competitors take market share from our products, or we may not win opportunities because our competitors have or are perceived to have more effective servicing or marketing or greater or more timely product availability;
- our competitors are able to obtain regulatory approvals for products or services or otherwise bring competing products to market earlier than us; or
- our competitors offer more competitive pricing or we fail to manufacture, in a cost-effective way, or at all, sufficient quantities of our products to meet customer demand.

Competitive and regulatory conditions in many markets in which we operate restrict our ability to fully recover through price increases, higher costs of acquired goods and services resulting from inflation, and other drivers of cost increases. Furthermore, the introduction of counterfeit products into the markets we serve may have the effect of eroding confidence in our products or in our industry as a whole. 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. If we are unable to compete successfully in this highly competitive industry, it could have a material effect on our business, financial condition and results of operations.

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

Our ability to retain customers, attract new customers, grow our business and enhance our brand depends on our success in developing and delivering products and services that meet our customers' needs and expectations. We devote a significant amount of financial and other resources to researching and developing new technologies, products, services and markets. The development, manufacture and sale of diagnostic products and services and new technologies require a significant investment of

resources, such as employee time, offices and R&D and manufacturing facilities, and development of new partners and channels. Furthermore, developing and manufacturing new products and services require us to anticipate customers' and patients' needs and emerging technology trends accurately. We may experience R&D, manufacturing, regulatory, marketing and other difficulties that could delay or prevent our introduction of new or enhanced products and services. The R&D process in the healthcare industry generally takes a significant amount of time from design stage to product launch. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. In addition, innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursements. In the event of such failure, we may need to abandon a product or service in which we have invested substantial resources.

We cannot be certain that:

- any of our products or services under development will be successfully developed, or if developed, will be timely introduced to the market;
- any of our products or services under development will prove to be safe and effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, necessary regulatory approvals;
- the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or
- these products and services, if and when approved, can be successfully marketed or will be adopted in the market.

These factors, as well as supply, manufacturing or distribution problems or other factors beyond our control, could delay the launch of new products or services. If we are unable to deliver reliable products in a timely manner, promptly respond to and address quality issues, provide expected levels of customer service, and comply with applicable regulations and rules, our ability to deliver products that meet our customers' needs and expectations and our competitive position, branding and results of operations may be adversely and materially affected.

Global market, macroeconomic and geopolitical conditions may adversely affect our operations and performance.

The growth of our business and demand for our products and services are affected by changes in the health of the overall global economy and, in particular, of the healthcare industry. Demand for our products and services could change more dramatically than in previous years based on funding and reimbursement constraints and support levels from governments, universities, hospitals and the private industry, including laboratories. Our global business is adversely affected by decreases in the general level of economic activity, such as decreases in business and consumer spending, increases in unemployment rates, the inflationary environment, rising interest rates, the recessionary environment, and budgeting constraints of governmental entities. Disruptions in the U.S., Europe or in other economies, including due to geopolitical conflict, including the ongoing conflict in Ukraine and rising tensions between China and Taiwan, or weakening of emerging markets, including China, could adversely affect our sales, profitability and/or liquidity.

A future deterioration in financial markets or confidence in major economies or other macroeconomic developments could affect businesses such as ours in a number of ways. A tightening of credit in financial markets could adversely affect the ability of our customers and suppliers to obtain financing for significant purchases and operations, could result in a decrease in or cancellation of orders for our products and services and could impact the ability of our customers to make payments. Similarly, a tightening of credit may adversely affect our supplier base, increase the potential for one or more of our suppliers to experience financial distress or bankruptcy, and could also impact our operations more directly, including any outstanding or contemplated credit facility or other borrowings. Our financial position, results of operations and cash flows could be materially adversely affected by difficult conditions and volatility in the capital, credit and commodities markets.

Fluctuations or a decline in sales of our COVID-19 and influenza diagnostic tests can have a significant impact on our operating results and if sales or revenues of our COVID-19 or influenza tests fluctuate or decline for any reason, our operating results could be materially and adversely affected.

A significant percentage of our total revenues is generated from a limited number of our product families. In particular, revenues from the sales of our COVID-19 tests have represented a significant portion of our total revenues. Sales of our COVID-19 products accounted for approximately 44% of our total revenues for the year ended January 1, 2023, which includes the impact of Ortho's operations from the date of the Combinations. Demand for our COVID-19 testing products has and may continue to fluctuate or decline as a result of a number of factors, including but not limited to the emergence and impact of new variants or resurgences, the effectiveness of global containment efforts, and the increased market supply of COVID-19 tests by our competitors. Sales of our influenza tests accounted for approximately 11% of our total revenues for the year ended January 1, 2023, which includes the impact of Ortho's operations from the date of the Combinations. Demand for our influenza tests can fluctuate or decline based on the severity of the flu season. The gross margins derived from sales of our COVID-19 and influenza tests are generally 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 fluctuate or 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 from the FDA for our COVID-19 products, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis.

A significant portion of our total revenues are from a relatively small number of customers, and if we fail to retain or expand our customer relationships or significant customers terminate or do not renew their contracts, our business, operating results and financial condition could be adversely affected.

A significant portion of our revenues are from sales of products and services to distributors. Although we have many distributor relationships in the U.S. and globally, the market is dominated by a small number of these distributors and as a result, we rely on certain key distributors for the sales of some of our products. 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. In addition, our efforts to distribute our products directly in some markets may be unsuccessful. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales.

In addition to distributors, we also have a number of other customers who are significant. If our relationships with such customers are terminated, or such customers do not renew their contracts with us, or substantially reduce or stop ordering from us, and if we do not add new large customers over time, our business could be harmed. Our ability to continue to generate revenue from our significant customers will depend on our ability to maintain strong relationships with these customers and introduce competitive new products and services at competitive prices. Moreover, customer consolidation could reduce the number of customers and may increase the risk of our dependence on a small number of customers. Government agencies are also important customers, and in fiscal year 2022, have represented significant revenues. Our ability to procure further government contracts will depend on a number of factors, including the general level of support for testing, including for COVID-19, other macroeconomic and geopolitical conditions, budgeting constraints of governmental entities, tendering requirements and funding, and there can be no assurance that we will procure additional contracts, or if procured, the timing, pricing or amount contracted.

If total revenues from some of our significant customers were to decrease or not continue in any material amount in the future, or if we are not successful in growing our current or new customer relationships or timely transitioning our 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.

Interruptions and delays 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, suppliers and vendors for some of our materials, components, equipment, packaging and other products and services. Any change in our relationship with our contract manufacturers, suppliers of raw materials and other third-party vendors or changes to contractual terms of our agreements with any of them could adversely affect our financial condition and results of operations. Further, 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, or the cost of such supplies may be significantly greater. Our reliance on a small number of contract manufacturers and a large number of single and sole source suppliers makes us vulnerable to possible capacity or other production constraints of such suppliers or in their supply chain, reduced control over product availability, delivery schedules and costs and reduced ability to monitor compliance with our product manufacturing specifications.

As a result of the COVID-19 pandemic and other macroeconomic and geopolitical conditions, including inflationary pressures, general economic slowdown or a recession, rising interest rates, foreign exchange rate volatility and changes in monetary policy, we have experienced shortages and delays in receiving certain raw materials and other components for our products and have experienced logistics and distribution challenges, as well as challenges in labor availability and rising labor costs, all of which have affected our ability to fulfill customer orders, including instrument placements, on a timely basis. Supply chain, production, logistics and distribution challenges, including shortages of raw materials and components, cost inflation, shipping delays, labor availability constraints and rising labor costs, have impacted, and we expect will continue for some period of time to impact, our results of operations. As a result, we are currently encountering, and may continue to encounter, increased customer backlogs of orders and inventory shipments out of our warehouse facilities. If these increased customer backlogs continue, they may adversely impact customer relationships and affect our financial performance.

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

In addition, due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost. For example, stringent requirements of the FDA and other regulatory authorities regarding the manufacture of certain of our products may prevent us from quickly establishing additional or replacement sources for the raw materials, products, components or manufacturing services that we use, or from doing so without excessive cost. Further, our suppliers may be subject to regulation by the FDA and other regulatory authorities that could hinder their ability to produce necessary raw materials, products and components. 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.

If our current contract manufacturers, suppliers of raw materials and other third-party vendors are unable or unwilling to manufacture or supply our products or components or requirements for raw materials in required volumes and at required quality levels or renew existing terms under supply agreements, we may be required to replace such manufacturers, suppliers and vendors and may be unable to do so in a timely or cost-effective manner, or at all. 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, financial condition and operating results.

We may experience manufacturing or warehousing problems or delays due to, among other reasons, our volume, specialized processes, and macroeconomic and geopolitical conditions.

The global supply of some of our products depends on the uninterrupted efficient operation of our manufacturing facilities, and the continued performance of our contract manufacturers, suppliers of raw materials and other third-party vendors under our contractual arrangements. Many of our manufacturing processes are complex and involve sensitive scientific processes involving the use of unique and often proprietary antibodies and other raw materials that cannot be replicated or acquired through alternative sources without undue delay or expense. Other processes present difficult technical challenges to obtain the manufacturing yields necessary to operate profitably. In addition, our manufacturing processes may require complex and specialized equipment, which can be expensive to maintain, repair or replace with required lead times of up to a year.

The manufacturing of certain of our products is concentrated in one or more of our manufacturing plants or those of our suppliers, with no or limited alternate 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, damage to our equipment or one or more of our facilities, or any other event that negatively impacts our manufacturing process, facilities, systems or equipment, or the process, facilities, systems or equipment of our contract manufacturers or suppliers, could delay, reduce, suspend or terminate shipments of products or the release of new products or could result in the delivery of inferior products. In such circumstances, our revenue from the affected products would decline and we could incur losses until such time as we or our contract manufacturers are able to restore or rebuild our or their production processes or we are able to put in place alternative contract manufacturers or suppliers. Similarly, any disruption or other operational challenges to one of our primary warehouse facilities could result in decreased revenue or increased costs given the challenge in finding suitable alternative facilities.

Our collaboration arrangements may not operate according to our business strategy if our collaboration arrangement partners fail to fulfill their obligations.

As part of our business, we are party to collaboration arrangements with other companies, including the Joint Business with Grifols, and we may enter into additional collaboration arrangements in the future. The nature of a collaboration arrangement requires us to share control over significant decisions with unaffiliated third parties. For example, governance of the Joint Business is shared with Grifols through a supervisory board made up of equal representation by us and Grifols. The supervisory board is responsible for all significant decisions relating to the Joint Business that are not exclusively assigned to either us or Grifols under the contract that established the Joint Business. Since we may not exercise exclusive control over our current or

future collaboration arrangements, we may not be able to require our collaboration arrangement partners to take actions that we believe are necessary to implement our business strategy. Disputes between us and our collaboration arrangement partners could also result in litigation, which can be expensive and time-consuming. Additionally, differences in views among collaboration arrangement partners may result in delayed decisions or failures to agree on major issues. If these differences cause our collaboration arrangements to deviate from our business strategy, our results of operations could be materially adversely affected.

Unexpected increases in, or inability to meet, demand for our products and services could require us to spend considerable resources to meet such 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, including as a result of manufacturing or warehousing problems or supply shortages or shortfalls, could harm our customer relationships and impair our reputation within the industry. For instance, we are currently encountering, and may continue to encounter, increased customer backlogs of orders and inventory shipments out of our warehouse facilities, due to a number of factors. Further, if we experience unexpected increases in the demand for our products or services or supply shortages or shortfalls, we may be required to incur additional costs to meet these demands. These costs could involve purchasing or producing safety stock of components or products, purchasing new machinery or obtaining additional labor resources or even the cost of acquiring or constructing new manufacturing facilities. This would increase our capital and other costs, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing and production capabilities in a timely manner, our total revenues could be adversely affected. 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.

A decrease in the number of surgical procedures performed, and the resulting decrease in blood demand, could negatively impact our financial results.

Our immunohematology and donor screening products are frequently used in connection with the testing of blood prior to transfusion, which is typically associated with surgical procedures. A decrease in the number of surgeries being performed in the markets in which we operate could result in decreased demand for blood for transfusions, which would in turn result in lower testing volumes and, therefore, decreased sales of our products. For example, we believe markets in developed countries have, at times, seen a decrease in the number of surgical procedures and lower demand for blood in recent years. A decrease in the number of surgical procedures performed could result from a variety of factors, such as fewer elective procedures and the improved efficacy and popularity of non-surgical treatments. In addition to lower surgical volumes, blood demand could also be negatively affected by more efficient blood utilization by hospitals. Blood is a large expense for hospital laboratories and pressure on hospital budgets due to macroeconomic factors and healthcare reform could force changes in the ways in which blood is used. Fewer surgeries and lower blood demand could negatively impact our revenue, profitability and cash flows.

Our reagent rental model reduces our cash flows during the initial part of the applicable contract, which causes our cash flows to fluctuate from quarter to quarter.

Leases, rather than sales, of instruments under our reagent rental model have the effect of reducing cash flows during the initial part of the applicable contract as we support those commercial transactions until we are able to recover our investment over the life of the contract. The use of cash in connection with this model causes our cash flows to fluctuate from quarter to quarter and may have a negative effect on our financial condition.

We may not achieve market acceptance of our products among physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other POC settings, blood banks and donor centers, individual, non-professional OTC customers, or other customers, and this would have a negative effect on future sales.

We maintain customer relationships with numerous physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other POC settings, blood banks and donor centers, individual, non-professional OTC customers and other customers. We believe that sales of our products depend significantly on our customers' confidence in, and recommendations of, our products. In addition, in a number of cases, our success depends on technicians' acceptance and confidence in the effectiveness and ease-of-use of our products, including our new products. If we do not capture sales at the levels anticipated in our budget, our total revenues will not be at the levels that we expect and the costs we incur or have incurred may be disproportionate to our sales levels.

In order to achieve acceptance by healthcare professionals, we seek to educate the healthcare community as to the distinctive characteristics, perceived benefits, clinical efficacy and cost-effectiveness of our products compared to alternative products, including the products offered by our competitors. Acceptance of our products also requires effective training of healthcare

professionals in the proper use and application of our products. Failure to effectively educate and train our technician end-users, continue to develop relationships with leading healthcare professionals or achieve market acceptance from healthcare providers or other customers with respect to the use of our diagnostic products could result in less frequent acceptance or recommendations of our products, which may adversely affect our sales and profitability.

The healthcare industry and related industries that we serve have undergone, and are in the process of undergoing, significant changes in an effort to reduce costs, which could adversely affect our business, financial condition and results of operations.

The healthcare industry and related industries that we serve have undergone, and are in the process of undergoing, significant changes in an effort to reduce costs. Many of our customers, and the end-customers to whom our customers provide products, rely on private or government funding of and reimbursement for healthcare products and services and research activities. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payors, principally private health insurance plans and federal Medicare and Medicaid, to reimburse all or part of the cost of the procedure. For example, MACRA repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. In 2018, CMS implemented certain provisions of PAMA, which made substantial changes to the way in which clinical laboratory services are paid under Medicare. The revised reimbursement methodology under PAMA results in relatively lower reimbursement under Medicare for clinical diagnostic lab tests than has been historically available. These legislative changes in the U.S., healthcare austerity measures in Europe and other potential global healthcare reform changes and government austerity measures may reduce the amount of government funding or reimbursement available to customers or end-customers of our products and services and/or the volume of medical procedures using our products and services. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, legislative amendments, regulation or reimbursement policies of third-party payors may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

Governmental and private healthcare providers and payors around the world are increasingly utilizing managed care for the delivery of healthcare services, forming group purchasing organizations to improve their purchasing leverage and using competitive bid processes to procure healthcare products and services.

Health insurance premiums, co-payments and deductibles have also generally increased in recent years. These increases may cause individuals to forgo health insurance, as well as medical attention. This behavior may reduce the demand for certain of our diagnostics products and services.

The foregoing changes in the healthcare industry and related industries that we serve may cause participants in the healthcare industry to purchase fewer of our products and services, reduce the prices they are willing to pay for our products or services, reduce the amounts of reimbursement and funding available for our products or services from governmental agencies or third-party payors, reduce the volume of medical procedures that use our products and services and increase our compliance and other costs. Moreover, we believe 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.

Any of the factors described above could adversely affect our business, financial condition and results of operations.

Consolidation of our customer base and the formation of group purchasing organizations could materially adversely affect our sales and results of operations.

Consolidation among healthcare providers and the formation of buying groups and, with respect to our international operations, government-sponsored tendering processes, have put pressure on pricing and sales of our products, and in some instances, required payment of fees to group purchasing organizations or required us to provide lower pricing in the tendering process. Our success in these areas depends partly on our ability to enter into contracts with integrated health networks and group purchasing organizations. If we are unable to enter into contracts with these group purchasing organizations and integrated health networks on terms acceptable to us or if we fail to have our pricing terms accepted in the tendering process, our sales and results of operations may be adversely affected. Even if we are able to enter into these contracts or have our pricing terms accepted in the tendering process, they may be on terms that negatively affect our current or future profitability. Furthermore, given the average industry contract length for our Ortho instruments is five to seven years, if we are unable to enter into a contract with a new customer or renew a given contract with an existing customer, it may be several years before we have an opportunity to acquire or reacquire, as applicable, such customer's business, which may have a material adverse effect on our results of operations in the interim period.

We may engage in acquisitions and divestitures, and may encounter difficulties integrating acquired businesses with, or disposing of divested businesses from, our current operations; therefore, we may not realize the anticipated benefits of these acquisitions and divestitures.

We may seek to grow through strategic acquisitions. Our due diligence reviews of our acquisition targets may not identify all of the material issues necessary to accurately estimate the cost or potential loss contingencies with respect to a particular transaction, including potential exposure to regulatory sanctions resulting from an acquisition target's previous activities as well as potential vulnerability to cybersecurity risks. We may incur unanticipated costs or expenses, including post-closing asset impairment charges, expenses associated with eliminating duplicate facilities, litigation and other liabilities. We also may encounter difficulties in integrating acquisitions with our operations, applying our internal controls processes to these acquisitions, retaining key technical and management personnel, complying with regulatory requirements, or in managing strategic investments. Additionally, we may not achieve the benefits we anticipate when we first enter into a transaction in the amount or timeframe anticipated, if at all. Any of the foregoing could adversely affect our business and results of operations. In addition, accounting requirements relating to business combinations, including the requirement to expense certain acquisition costs as incurred, may cause us to experience greater earnings volatility and generally lower earnings during periods in which we acquire new businesses. We may also make strategic divestitures from time to time. These divestitures may result in continued financial involvement in the divested businesses, such as through guarantees, indemnity obligations or other financial arrangements, following those transactions. Under these arrangements, nonperformance by those divested businesses could result in financial obligations imposed upon us and could affect our future financial results.

Natural disasters, public health crises, geopolitical 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 areas vulnerable to wildfire, which make us susceptible to earthquake and fire risk. We also have significant operations in Rochester, New York, Raritan, New Jersey, Pencoed, Wales and Pompano Beach, Florida. 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.

Further, as a multinational company with a large international footprint, we are also subject to increased risk of damage or disruption to us, our employees, facilities, partners, suppliers, distributors, resellers or customers due to terrorist acts, civil unrest, conflicts, wars, adverse weather conditions, natural disasters, power outages, pandemics, endemics or other public health crises and environmental incidents, wherever located around the world. The potential for future terrorist attacks and natural disasters, the national and international responses to such attacks and natural disasters or perceived threats to national security and other actual or potential conflicts or wars may create macroeconomic and geopolitical uncertainties. In addition, as a multinational company with headquarters and significant operations located in the U.S., actions against or by the U.S., including sanctions, could result in a decrease in demand for our products, make it difficult or impossible to deliver products to our customers or to receive components from our suppliers, create delays and inefficiencies in our supply chain and pose risks to our employees, resulting in the need to impose travel restrictions. Any interruption in production capability could require us to make substantial capital expenditures to remedy the situation, if it can be remedied, which could negatively affect our profitability and financial condition. 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 Relating to Our International Operations

As a global business, we face risks relating to our non-U.S. operations and international sales, including inherent macroeconomic, geopolitical and regulatory risks, that could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy.

We conduct our business on a global basis, as our products are sold internationally, with the majority of our international sales to our customers in our EMEA and China regions. Our international operations are subject to inherent macroeconomic, geopolitical and regulatory risks, which could impact our financial performance, cause interruptions in our business operations and impede our international growth. These foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing product registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations;
- compliance with complex foreign and U.S. laws and regulations that apply to our international operations, including U.S. laws 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;

- lost revenue as a result of macroeconomic developments, including the inflationary environment and recessionary fears;
- the imposition by foreign governments of trade barriers such as tariffs, quotas, preferential bidding, import restrictions or other barriers;
- exposure to currency exchange fluctuations against the U.S. dollar;
- decreased liquidity resulting from longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection and enforcing agreements through foreign legal systems;
- lower productivity resulting from difficulties we may encounter in staffing and managing sales, support and R&D operations across many countries;
- difficulties associated with navigating foreign laws and legal systems;
- difficulties in identifying potential third-party distributors or distribution channels;
- import or export licensing requirements, both by the U.S. and foreign countries;
- international sanctions regimes, including sanctions imposed by the U.S. on foreign countries;
- reduced, or lack of, protection for, and enforcement of, our intellectual property rights;
- social, geopolitical or macroeconomic instability in some of the regions where we currently sell our products or operate or that we may expand into in the future, including as a result of acts of war, including the ongoing conflict in Ukraine, and rising tensions between China and Taiwan, 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 resulting from international tax laws;
- transportation difficulties and delays resulting from inadequate local infrastructure; and
- diversion to the U.S. of our products sold into international markets at lower prices.

The occurrence of any of these, or other factors over which we do not have control, could lead to reduced revenue and profitability.

Currency translation risk and currency transaction risk may adversely affect our financial condition, results of operations and cash flows.

We transact business in numerous countries around the world and expect that a significant portion of our business will continue to take place in international markets. Because our financial statements are presented in U.S. dollars, we must translate earnings as well as assets and liabilities into U.S. dollars at exchange rates in effect during or at the end of each reporting period, as applicable. Therefore, increases or decreases in the value of the U.S. dollar against other currencies in countries where we operate will affect our results of operations and the value of balance sheet items denominated in foreign currencies. Furthermore, many of our local businesses generate revenues and incur costs in a currency other than their functional currency, which can impact the operating results for these operations if we are unable to mitigate the impact of foreign currency fluctuations. Accurately predicting the effects of exchange rate fluctuations upon our future operating results is difficult because of the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates. Accordingly, our profitability could be affected by fluctuations in foreign exchange rates. Given the volatility of exchange rates, we may not be able to effectively manage our currency transaction and/or translation risks, and any volatility in currency exchange rates may have an adverse effect on our financial condition, results of operations and cash flows. We have entered into hedging agreements to address certain of our currency risks and intend to utilize local currency funding of expansions when appropriate. We do not intend to hold financial instruments for trading or speculative purposes.

Continuing worldwide geopolitical and social uncertainty, including tariffs and trade measures, trade embargoes, trade wars and social tensions, may adversely affect our business, financial results and prospects, both domestically and internationally.

Geopolitical and social uncertainty in the U.S. and throughout the world, including due to the ongoing conflict in Ukraine and rising tensions between China and Taiwan, could impair political, trade and economic relations worldwide. Changes in policy in the U.S. and other countries regarding international trade, including import and export regulation and international trade agreements, could limit the countries in which some of our products may be manufactured or sold, or could restrict our access to, or increase the cost of obtaining, products from foreign sources. The occurrence of any of the foregoing could negatively impact our business, financial condition and results of operations.

Governments sometimes impose additional duties, tariffs or taxes on certain imported products. The imposition of import tariffs or restrictions, or other changes in U.S. trade policy, could trigger retaliatory actions by affected countries. For instance, the

U.S. and China have implemented import tariffs and retaliatory tariffs on certain categories of goods, including from time to time, some of our reagent products sold in China. These tariffs, depending upon their ultimate scope and value and how they are implemented, could negatively impact our business by affecting the demand for our products and services or the supply of materials we use to manufacture our products and increasing our costs, thereby making our products less cost competitive.

Risks Relating to Our IT Systems

Our ability to protect our information systems and electronic transmissions of personal data and sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.

We are highly dependent on IT networks and systems, including our office networks, operational environment, special purpose networks, systems and software used to operate our instruments and devices and those networks and systems managed by vendors or third parties, to securely process, transmit and store electronic information (including sensitive personal information and proprietary or confidential information). Our systems may prove inadequate to our business needs and necessary upgrades may not be available or operate as designed, which could result in excessive costs or disruptions in portions of our business. These risks may be heightened as we integrate the combined systems and operations of Quidel and Ortho. Like any large corporation, from time to time the information systems on which we rely, including those controlled and managed by third parties, may be subject to computer viruses, malicious software, attacks by hackers and other forms of cyber intrusions or unauthorized access, any of which can create system disruptions, shutdowns or unauthorized disclosure of sensitive data. In addition, a security breach that leads to disclosure of information protected by privacy laws could require us to comply with breach notification requirements under applicable laws, result in litigation or regulatory action, or otherwise subject us to liability under laws that protect personal data.

If we experience a significant technology incident, such as a serious product vulnerability or security breach, or any other disruptions, delays or deficiencies from our enterprise resource planning systems, it 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. If this happens, our revenues could decline and our business could suffer, and we may need to make significant further investments to protect data and infrastructure. An actual or perceived vulnerability, failure, disruption or breach of our network or privileged account security in our systems also could adversely affect the market perception of our products and services, as well as our perception among new and existing customers. Additionally, a significant security breach could result in theft of trade secrets and intellectual property, cause us to incur increased costs for insurance premiums and security remediation and subject us to potential liability, litigation and regulatory or other government action. If any of the foregoing were to occur, our business may suffer.

We attempt to mitigate the above risks by employing a number of measures, including monitoring and testing of our security controls, employee training and maintenance of protective systems and contingency plans. Further, our contractual arrangements with service providers aim to ensure that third-party cybersecurity risks are appropriately mitigated. We also maintain insurance relating to cybersecurity incidents, which we cannot guarantee will be adequate. It is impossible to eliminate all cybersecurity risk and thus our systems, products and services, as well as those of our service providers, remain potentially vulnerable to known or unknown threats. Additionally, our IT systems may also be vulnerable to damage or interruption from circumstances beyond our control, including fire, natural disasters, power outages and system failures.

Information security risks have generally increased in recent years because of the increased proliferation, sophistication and availability of complex malware and hacking tools to carry out cyber-attacks. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees with flexible work arrangements, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period of time. As cyber threats continue to evolve, we may be required to expend additional resources to mitigate new and emerging threats while continuing to enhance our information security capabilities or to investigate and remediate security vulnerabilities.

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, 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.

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 negatively impact our business.

Risks Relating to Our Intellectual Property

To remain competitive, we must continue to develop, obtain and protect 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 ours.

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, and our competitive position is therefore heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses to proprietary technology from others. We own significant intellectual property, including patents, patent applications, technology, trade secrets, know-how and trademarks in the U.S. and other countries, including, among others, Australia, Canada, China, various European countries, India, Japan and South Africa. We make strategic decisions on whether to apply for intellectual property protection and what kind of protection to pursue based on a cost-benefit analysis. While we endeavor to protect our intellectual property rights in certain jurisdictions in which our products are produced or used and in jurisdictions into which our products are imported, the decision to file for intellectual property protection is made on a case-by-case basis. Because of the differences in foreign trademark, patent and other laws concerning proprietary rights, our intellectual property rights may not receive the same degree of protection in foreign countries as they would in the U.S. Certain of our intellectual property rights are held through license agreements and collaboration arrangements with third parties. We also rely on trade secrets and certain other unpatented proprietary technology and it is possible that others will independently develop the same technology or otherwise obtain access to our unpatented technology. We license some of the rights to use our patents and know-how to third parties. Further, we rely on confidentiality agreements and other similar arrangements with our employees, consultants, advisors, collaborators and other persons who have access to our proprietary and confidential information, which may not provide meaningful protection for our proprietary 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. Failure to obtain or maintain adequate protection of our intellectual property rights for any reason, including failure to file patent or trademark applications successfully or at all, failure to obtain licenses on commercially reasonable terms if at all, failure to retain intellectual property rights upon termination of our licenses or collaboration agreements, or failure to police our intellectual property through our licensees, could have a material adverse effect on our business, results of operations and financial condition.

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 and services, require us to redesign our products or services 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. We are and have been subject to litigation with parties that claim, among other matters, that we infringed their patents or misappropriated 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.

Our customers may also 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. The defense and prosecution of patent and trade secret claims are both costly and time consuming and could divert management's attention from other business concerns. Moreover, an adverse determination in any of these types of disputes could prevent us from developing, using, manufacturing or selling some of our products or processes; limit or restrict the type of work that employees involved with such products may perform for us; require us to obtain a license on the disputed rights, which may not be available on commercially reasonable

terms, if at all; subject us to significant liability in the form of royalty payments, penalties, special and punitive damages and attorneys' fees; cause our distributors or end users to reduce or terminate purchases of our products; or require us to re-design our products or processes, any of which could materially and adversely affect our business, financial condition and results of operations.

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.

Risks Relating to Government Regulations

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 a public health 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. These EUA standards for marketing authorization are lower than if the FDA had reviewed our tests under its traditional marketing authorization pathways, and we cannot assure you that our tests would be cleared or approved under those more onerous clearance and approval standards. The FDA has also established certain conditions that must be met in order to maintain authorization under these EUAs. The requirements that apply to the manufacture and sale of these products may be unclear and are subject to change. The FDA may also waive otherwise applicable Consumer Good Manufacturing Practice requirements to accommodate emergency response needs. All of our current COVID-19 products used for testing for the COVID-19 virus were obtained under EUAs. We may also seek EUA approvals for our other products. 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 superior approved products exist. Changes to FDA regulations or requirements could require changes to our authorized tests, necessitate additional measures or make it impractical or impossible for us to continue to market our tests. The loss of one or more of our EUAs for our COVID-19 products, or any of our other products that receive EUAs, could have a material adverse effect on our business, results of operations, financial condition or cash flows.

If we are unable to obtain or maintain required clearances or approvals for the commercialization of our products in the U.S. and certain foreign countries, we will not be able to sell those products in such jurisdictions, which could negatively impact our results of operations.

Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval, clearances or authorizations for new products in the U.S. and certain foreign countries where we intend to sell our products. The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S. and globally. Regulatory clearance and approval can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. 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, regulatory processes are subject to change, and new or changed regulations can result in increased costs, unanticipated delays, or lengthened review times of our products. We may not be able to obtain U.S. and foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from selling our products in the U.S. or certain foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

In the U.S., the FDA regulates most of our products. Clearance or approval to commercially distribute new medical devices is received from the FDA through a 510(k) clearance, or through approval of a PMA application. Approval to commercially distribute biologics is received from the FDA through approval of a BLA and may also require state licensing for the movement of biologics products in interstate commerce. The FDA may deny 510(k) clearance because, among other reasons, it determines that our product is not substantially equivalent to another U.S. legally marketed device. The FDA may deny approval of a PMA or BLA because, among other reasons, it determines that our product is not sufficiently safe or effective. Failure to obtain FDA

clearance or approval would preclude commercialization in the U.S., which could materially and adversely affect our future results of operations.

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.

Modifications or enhancements to a cleared or approved product that could significantly affect safety or effectiveness, or that constitute a major change in the intended use of the product, could require new 510(k) clearances or possibly approval of a new PMA or BLA, or a supplement to those applications. 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 not to seek a new 510(k). If the FDA disagrees with our determinations and requires us to submit a new 510(k), PMA or PMA supplement, or BLA or BLA supplement for any product modification, we may be required to cease marketing such product or to recall the modified product until we obtain clearance, and we may be subject to civil, criminal, monetary and non-monetary penalties and damage to our reputation.

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.

If the results of clinical studies required to gain regulatory approval to sell our products are not available when expected, or do not demonstrate the safety and effectiveness of those products, we may be unable to sell those products.

Before we can sell certain of our products, we must conduct clinical studies intended to demonstrate that those products are safe and effective and perform as expected. The results of these clinical studies (which are experiments involving human patients having the diseases or medical conditions that the product is trying to evaluate or diagnose) are used to obtain regulatory clearance or approval from government authorities, such as the FDA. Conducting clinical studies is a complex, time-consuming and expensive process. In some cases, we may spend several years completing the necessary clinical studies.

If we fail to adequately manage our clinical studies, those clinical studies and corresponding regulatory clearances or approvals may be delayed or we may fail to gain clearance or approval for our products altogether. Even if we successfully manage our clinical studies, we may not obtain favorable results and may not obtain regulatory clearance or approval for the applicable product. If we are unable to market and sell our new products or are unable to obtain clearances or approvals in the time frame needed to execute our product strategies, our business and results of operations would be materially and adversely affected.

Our business is subject to substantial regulatory oversight, and our failure to comply with applicable regulations may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals.

Our businesses are extensively regulated by the FDA and other federal, state and foreign regulatory agencies. These regulations impact many aspects of our operations, including development, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, physician interaction and record-keeping. Any material failure by us to comply with such applicable governmental regulations could result in product recalls, the imposition of fines, restrictions on our ability to conduct or expand our operations or the cessation of all or a portion of our operations.

The FDA and corresponding foreign regulatory agencies may require post-market testing and surveillance to monitor the performance of cleared or approved products or may place conditions on any product clearances or approvals that could restrict the commercial applications of those products. The discovery of problems with a product may result in restrictions on the product, including withdrawal of the product from the market. In addition, in some cases we may sell products or provide services that are reliant on the use or commercial availability of third-party products, including medical devices or equipment, and regulatory restrictions placed upon any such third-party products could have a material adverse impact on the sales or commercial viability of our related products or services.

We are subject to routine inspection by the FDA and other agencies for compliance with such agency's requirements applicable to our products, including, without limitation, the FDA's Quality System Regulation and Medical Device Reporting requirements in the U.S., and other applicable regulations worldwide. Our manufacturing facilities and those of our suppliers and distributors also are, or can be, subject to periodic regulatory inspections.

We are also subject to laws relating to matters such as privacy, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur

significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against our distribution of products, termination of our service agreements by our customers, disgorgement of money, operating restrictions and criminal prosecution.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new or modified products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result of these factors. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may increase the time it takes for new or modified medical devices and biologics to be reviewed and/or cleared or approved by necessary government agencies, which would adversely affect our business.

We may encounter challenges entering into contracts with government entities due to government-sponsored tendering requirements, and any contracts that we have entered into or will enter into with government entities may involve future funding, compliance and possible sanctions risks.

We endeavor to enter into contracts with government entities for grant-funded projects or the sale of our products. This may require us to follow government-sponsored tendering processes involving stringent restrictions, including pricing restrictions, ESG requirements, and other compliance obligations. As a result, we may face challenges meeting such government sponsored-tendering requirements, and ultimately, may not be awarded such contracts with government entities.

In addition, any government contract that we have entered into or will enter into may expose us to higher potential liability than do other types of contracts due to government funding shortfalls, the government's right to terminate for convenience, heightened legal compliance requirements, and our inability to meet key deliverables and milestones. Government funding applicable to our government grant contracts may be limited, and there is no guarantee that budget pressure at the federal, state and local level or changing governmental priorities will not eliminate funding availability. In addition, government contracts typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting and other requirements. For example, our contracts with the U.S. government generally require us to comply with the Federal Acquisition Regulations, the FCA, the Procurement Integrity Act, the Buy American Act and the Trade Agreements Act. Government contracts subject us to government audits, compliance investigations and oversight proceedings. Government agencies routinely review and audit government contractors to determine whether they are complying with applicable 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 relating to any government contract that we have entered into or will enter into, or we fail an audit, we could be subject to various sanctions, including 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. Our immunohematology business in particular is subject to the risk of product liability claims, as even the slightest inaccuracies in a specimen's analysis can lead to critical outcomes in the life of a patient, thereby leaving little to no room for error in the precision and accuracy of such testing. In addition, our marketing of monitoring services may cause us to be subjected to various product liability or other claims, including, among others, claims that inaccurate monitoring results lead to injury or death, or, in the case of our toxicology monitoring services, the imposition of criminal sanctions. The risk of a product liability claim is also 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 the FDA could be alleged to be misleading or erroneous. If the FTC or the FDA alleges or establishes that any of our communications are misleading, we could be subject to litigation and material penalties and fines.

Depending on the corrective action we take to redress a product's deficiencies, we may be required to obtain new clearances or approvals before we may market or distribute the corrected device. 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 and decrease sales of our products, and we could also face additional regulatory enforcement action, including FDA warning letters, untitled letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Moreover, any product liability or other claim brought against us, regardless of merit, could be costly to defend and could result in an increase to our insurance premiums. If we are held liable for a claim, that claim could materially affect our business and financial condition.

We are subject to healthcare regulations that could result in liability, require us to change our business practices and restrict our operations in the future.

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the governments of states and foreign countries in which we conduct our business. In the U.S., these healthcare laws and regulations include the federal Physician Self-Referral Law, federal Anti-Kickback Statute, federal civil and criminal false claims laws, including the FCA, the federal Civil Monetary Penalties Law, the Health Insurance Portability and Accountability Act of 1996, the federal Physician Payments Sunshine Act, the federal Food, Drug, and Cosmetics Act, U.S. federal consumer protection and unfair competition laws, and state law equivalents of each of the foregoing, as further described in Part I, Item 1, "Business—Government Regulations" of this Annual Report.

These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. In particular, these laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements, as well as interactions with healthcare professionals through consultant arrangements, product training, sponsorships or other activities. Efforts to help ensure that our business arrangements with third parties comply with applicable healthcare and other laws and regulations involve substantial costs. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, governmental authorities may conclude that our business practices do not comply with healthcare laws and regulations.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, the medical device industry's relationship with physicians has been under increasing scrutiny by the U.S. Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ"), the state attorney generals and other foreign and domestic government agencies. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of federal or state governments, with potential liability under the FCA, including mandatory treble damages and significant per-claim penalties. Additionally, as a result of these investigations and qui tam actions, we may need to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation, or failure to comply with such investigation, including those led by the OIG or the DOJ, or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the federal and state laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, oversight if we become subject to a consent decree or corporate integrity agreement, and disgorgement, and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

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

Our operations and facilities are subject to various foreign, federal, state and local environmental, health and safety laws, rules, regulations and other requirements, including those governing the generation, use, manufacture, handling, transport, storage, treatment and disposal of, or exposure to, regulated materials, discharges and emissions to air and water, the cleanup of contamination and occupational health and safety matters. Compliance with such laws and regulations requires significant effort and costs. For example, our R&D 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, the Resource Conservation and Recovery Act, and the Clean Water Act, among other laws and regulations. Noncompliance with such laws and regulations can result in fines or penalties or limitations on our operations or liability for remediation costs, as well as claims alleging personal injury, property, natural resource or environmental damages.

We may also incur liability as a result of any contamination or injury arising from a release of or exposure to such regulated hazardous materials. Under some environmental laws and regulations, we could also be held responsible for costs relating to any contamination at our past or present facilities and at third-party disposal sites where we have sent wastes for treatment or disposal. Liability for contamination at contaminated sites may be imposed without regard to whether we knew of, or caused, the release or disposal of such regulated substances and, in some cases, liability may be joint or several. Any such future expenses or liability could have a negative impact on our financial condition and results of operations.

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 requirements or 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, our workers, properties and equipment may be exposed to potential operational hazards such as fires, safety incidents, releases of regulated materials, malfunction of equipment, accidents and natural disasters, which could result in personal injury or loss of life, damage to or destruction of property and equipment or environmental damage, and could potentially result in a suspension of operations, harm to our reputation and the imposition of civil or criminal fines or penalties, all of which could adversely affect our business.

We will be exposed to significant risks in relation to compliance with anti-corruption laws and regulations and economic sanctions programs.

Doing business on a worldwide basis requires us to comply with the laws and regulations of the U.S. government and those of various international and sub-national jurisdictions, and our failure to successfully comply with these rules and regulations may expose us to liabilities. These laws and regulations apply to companies and individual directors, officers, employees and agents, and may restrict our operations, trade practices, investment decisions and partnering activities. In particular, our international operations are subject to U.S. and foreign anti-corruption laws and regulations, such as the FCPA, the Bribery Act and the Brazilian Anti-Bribery Act, among others, and economic and trade sanctions, including those administered by the United Nations, the E.U., the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC") and the U.S. Department of State. The FCPA prohibits providing anything of value to foreign officials for the purposes of obtaining or retaining business or securing any improper business advantage. We may deal with state-owned business enterprises, the employees and representatives of which may be considered foreign officials for purposes of the FCPA. We are subject to the jurisdiction of various governments and regulatory agencies outside of the U.S., which may bring our personnel into contact with foreign officials responsible for issuing or renewing permits, licenses or approvals or for enforcing other governmental regulations. The provisions of the Bribery Act extend beyond bribery of foreign public officials and are more onerous than the FCPA in a number of other respects, including jurisdiction, non-exemption of facilitation payments and penalties. Economic and trade sanctions restrict our transactions or dealings with certain sanctioned countries, territories and designated persons, absent authorizations or exemptions under applicable law, such as OFAC's licenses permitting certain humanitarian trade.

While we endeavor to have a strong culture of compliance and an adequate system of internal controls, including procedures to minimize and detect fraud in a timely manner, as well as processes for complying with OFAC authorizations or exemptions, there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and prevent violations of the applicable laws by one or more of our employees, consultants, agents or partners and, as a result, we could be subject to penalties and material adverse consequences on our business, financial condition or results of operations.

Our collection, use and disclosure of personal information, including health information, is subject to federal and state privacy and security regulations, as well as data privacy and security laws outside the U.S., including in the EEA, the U.K. and the People's Republic of China, and our failure to comply with those laws and regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

We and our partners may be subject to federal, state and foreign data protection laws, regulations and other obligations as further described in Part I, Item 1, "Business—Government Regulations" of this Annual Report.

The legislative and regulatory landscape for privacy and data protection continues to evolve, with jurisdictions in which we operate and in which our customers operate adopting or considering adopting new privacy and data security laws and regulations regarding the collection, use, processing and storage of information obtained from consumers and other end users, including health-related information. We may also be bound by contractual obligations with our customers relating to privacy, data protection and information security that are more stringent than applicable privacy laws and regulations, and some companies often will not contract with vendors that do not meet more rigorous standards.

Complying with these various laws, regulations, standards and contractual obligations could cause us to incur substantial costs, require us to change our business practices in a manner adverse to our business (including limiting our ability to collect, control, process, share, disclose and otherwise use personal data (including health and medical information which are subject to strict requirements)), reduce demand for certain of our digital solutions, restrict our ability to offer certain digital solutions in certain jurisdictions or subject us to sanctions, investigations, fines, penalties or other inquiries by U.S., federal, state and foreign data protection regulations, all of which could negatively impact our business or reputation. Moreover, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply, further increasing costs to comply, and increasing risks of potential failures or perceived failures to comply. Because many of these laws and regulations are new, it is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as many of the laws are drafted broadly and leave great discretion to the relevant government authorities to exercise.

Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, including as a cost of doing business, or due to new or increasing fines or penalties for privacy and cybersecurity violations, damage our reputation, and adversely affect our business and results of operations. Further, a cyber-attack or other data breach affecting sensitive personal information, including health information, could also result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business, including under these same laws and contractual obligations.

We continue to monitor the evolving data protection landscape to support our efforts to comply with the requirements in the countries in which we do business.

We are subject to U.S. and foreign tax laws, and changes to such tax laws or differing interpretation of those laws by the relevant governmental authorities could adversely affect us.

The U.S. Congress, the Organisation for Economic Co-operation and Development and other government agencies in jurisdictions where we do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. Thus, the tax laws in the U.S., the U.K. and other countries in which we do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

In addition, the tax laws and regulations in the U.S., the U.K. and the numerous other jurisdictions in which we operate are inherently complex, and we are and will be obligated to make judgments and interpretations about the application of these laws and regulations to us and our operations and businesses. Our interpretation and application of these laws and regulations could be challenged by the relevant governmental authorities, which could result in material administrative or judicial procedures, actions or sanctions.

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

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

We continue to monitor changes in tax laws in the U.S. and the impact of proposed and enacted legislation in the various foreign jurisdictions in which we operate. President Biden has provided informal guidance on tax law changes he may support.

Among other things, proposed changes would raise the rate on both domestic and foreign income. If any of these proposals are ultimately enacted into legislation, they could materially impact our tax provision, cash tax liability and effective tax rate.

Legislative or taxation changes or HM Revenue & Customs ("HMRC") enforcement actions may have a material adverse impact on our business, results of operations and financial condition.

We are subject to the laws of England and Wales and the taxation rules administered by HMRC. Changes in legislation or regulations and actions by regulators, including changes in administration and enforcement policies, could from time to time require operational improvements or modifications, including in relation to the conduct of reviews and audits, that could result in higher costs or restrict our ability to operate our business and, as a result, have a material adverse effect on our business, results of operations and financial condition. HMRC may also take enforcement actions against us which may result in fines, penalties and/or interest charges being imposed on us which may have a material adverse effect on its business, results of operations and financial condition.

Risks Relating to Corporate Finance

We may need to raise additional funds to finance our future capital or operating needs or other business purposes, which could have adverse consequences on the interests of our stockholders, and may not be available on acceptable terms or at all.

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

Our indebtedness could adversely affect our financial condition, limit our ability to raise additional capital to fund our operations and prevent us from fulfilling our obligations under our indebtedness.

Our Credit Agreement governs our senior secured credit facilities, which consists of (i) a Term Loan in an original amount of $2,750.0 million and (ii) a $800.0 million Revolving Credit Facility (each capitalized term as defined in this Annual Report). As a result of our indebtedness, a portion of our cash flows will be required to pay interest and principal on our outstanding indebtedness, and we may not generate sufficient cash flows from operations, or have future borrowings available under the Revolving Credit Facility, to enable us to repay our indebtedness or to fund our other liquidity needs. As of January 1, 2023, we had total indebtedness of $2,638.3 million, and we had availability under our Revolving Credit Facility of $786.9 million (net of $13.1 million of outstanding letters of credit).

Subject to the limits contained in the Credit Agreement, we may incur additional debt from time to time to finance working capital, capital expenditures, investments or business acquisitions, or for other purposes. If we do so, the risks related to our higher level of debt would increase. Specifically, our higher level of debt could have important consequences to us and our stockholders, including:

- making it more difficult for us to satisfy our obligations with respect to our debt, and if we fail to comply with these obligations, an event of default could result and our credit worthiness may be impacted;
- limiting our ability to refinance or obtain additional financing to fund future working capital, capital expenditures, investments or other general corporate requirements;
- limiting us from making strategic acquisitions or causing us to make non-strategic divestitures;
- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, investments and other general corporate purposes;
- exposing us to the risk of increased interest rates as our borrowings under the credit facilities are at variable rates of interest;
- the Credit Agreement contains, 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;

- increasing our vulnerability to, and reducing our flexibility to respond to, changes in our business and industry, general economic downturns and adverse industry and business conditions;
- to the extent the debt we incur requires collateral to secure such indebtedness, exposing our assets to risks and limiting our flexibility related to such assets;
- any default under our Credit Agreement may result in proceedings against collateral we have used to secure the credit facilities, including substantially all of our and our guarantor subsidiaries' assets;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete and to changing business and economic conditions;
- placing us at a disadvantage compared to less leveraged competitors and affecting our ability to compete; and
- increasing our cost of borrowing.

The occurrence of any one of the foregoing risks could have a material adverse effect on our business, financial condition, results of operations and ability to satisfy our obligations in respect of our outstanding debt.

Furthermore, borrowings under our credit facilities are at variable rates of interest and expose us to interest rate risk. Recently, interest rates have increased from historically low levels. If interest rates continue to increase, our debt service obligations on our variable rate indebtedness will increase even though the amount borrowed may remain the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease. We have entered into a series of interest rate cap and interest rate swap agreements to hedge our interest rate exposures related to our variable rate borrowings under the credit facilities. However, it is possible that these interest rate cap and interest rate swap agreements or any future interest rate cap agreements or swaps we enter into may not fully or effectively mitigate our interest rate risk and we may decide not to maintain interest rate swaps in the future.

We may not be able to generate sufficient cash flows from operating activities to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our business, financial position and results of operations and our ability to satisfy our debt obligations.

Additionally, if we cannot make scheduled payments on our debt, we will be in default, and the lenders under the credit facilities could terminate their commitments to loan additional money to us, the lenders could foreclose against the assets securing their borrowings and we could be forced into bankruptcy or liquidation. All of these events could result in our stockholders losing all or a part of their investment.

Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to financial, business, legislative, regulatory and other factors beyond our control. We might not be able to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. The Credit Agreement restricts our ability to dispose of assets and use the proceeds from such dispositions and may also restrict our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. Because of these restrictions, we may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations then due.

In addition, we conduct all of our operations through our subsidiaries, some of which are not guarantors of our indebtedness. Accordingly, repayment of our indebtedness is dependent on the generation of cash flows by our subsidiaries and their ability to make such cash available to us, by dividend, debt repayment or otherwise. Unless they are guarantors of our indebtedness, our subsidiaries do not have any obligation to pay amounts due on our indebtedness or to make funds available for that purpose. Our subsidiaries may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each subsidiary is a distinct legal entity, and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries. While the Credit Agreement limits the ability of our subsidiaries to incur consensual restrictions on their ability to pay dividends or make other intercompany payments to us, these limitations are subject to qualifications and exceptions. In the event that we do not receive distributions from our subsidiaries, we may be unable to make required principal and interest payments on our indebtedness.

The terms of the Credit Agreement impose restrictions that may limit our current and future operating flexibility, particularly our ability to respond to changes in the economy or our industry or to take certain actions, which could harm our long-term interests and may limit our ability to make payments on our indebtedness.

The Credit Agreement contains a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interest, including restrictions on our ability, and the ability of our subsidiaries, to:

- incur additional indebtedness and guarantee indebtedness;
- pay dividends or make other distributions in respect of, or repurchase or redeem, capital stock;
- prepay, redeem or repurchase certain indebtedness;
- make business acquisitions;
- make loans and investments;
- sell, transfer or otherwise dispose of assets;
- incur liens;
- enter into transactions with affiliates;
- enter into new lines of business or alter the businesses we conduct;
- designate any of our subsidiaries as unrestricted subsidiaries;
- enter into agreements restricting our subsidiaries' ability to pay dividends; and
- consolidate, merge, transfer or sell all or substantially all of our assets or the assets of our subsidiaries.

In addition, the Credit Agreement requires us to comply with two financial covenants consisting of a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) and a minimum Consolidated Interest Coverage Ratio (as defined in the Credit Agreement). See Note 8 to the Consolidated Financial Statements for more information related to our financial covenants.

Our ability to comply with these covenants may be affected by circumstances and events beyond our control, such as prevailing economic conditions and changes in regulations, and we cannot assure you that we will be able to comply with such covenants. These restrictions also limit our ability to obtain future financings to withstand a future downturn in our business or the economy in general. Further, in order to respond to market conditions, we may need to seek waivers of various provisions in the Credit Agreement and we might not be able to obtain such waivers on reasonable terms, if at all.

Risks Relating to Our Employees

We may have difficulty attracting, motivating and retaining executives and other key employees.

Our success will depend in part upon our ability to attract, retain and motivate executives and sales, marketing, manufacturing, technical, scientific, technology and other key personnel. Competition for qualified personnel can be intense, both in the industry in which we operate and where our operations are located. Further, our current and prospective employees may experience uncertainty about the effect of the Combinations, which may impair our ability to attract, retain and motivate executives and other key personnel. The loss of any executive or other key personnel, particularly key manufacturing, R&D and technical personnel, could harm our business and prospects and could impede the achievement of our R&D, operations or strategic objectives.

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 Quidel and Ortho may be more difficult and our business may be harmed. Furthermore, we 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 our business and 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 the Company. Accordingly, no assurance can be given that we will be able to attract or retain key employees to the same extent that Quidel and Ortho were able to attract or retain employees in the past.

In addition, pursuant to severance provisions in legacy Quidel and Ortho executive employment agreements, certain of our employees are entitled to receive severance payments upon certain qualifying terminations of their employment. These 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. For example, such circumstances could occur in connection with the integration of Quidel and Ortho as a result of changes in roles and responsibilities.

If we are required to make unexpected payments to any pension plans applicable to our employees, our financial condition may be adversely affected.

Some of our current and former employees participate or participated in defined benefit pension plans that were sponsored by Ortho prior to the closing of the Combinations. We assumed certain underfunded and unfunded net pension liabilities of approximately $33.0 million in relation to these plans. Several of these plans are unfunded and, while we do not believe the liabilities in relation to these plans are significant, they will need to be satisfied as they mature from our cash resources. In jurisdictions where the defined benefit pension plans are intended to be funded with assets in a trust or other funding vehicle, we expect that, while not significant, the liabilities will exceed the corresponding assets in each of the plans. Various factors, such as changes in actuarial estimates and assumptions (including in relation to life expectancy, discount rates and rates of return on assets), as well as actual return on assets, can increase the expenses and liabilities of the defined benefit pension plans. The assets and liabilities of the plans must be valued from time to time under applicable funding rules and as a result we may be required to increase the cash payments we make in relation to these defined benefit pension plans.

We could also be required in some jurisdictions to make accelerated payments up to the full buy-out deficit in our defined benefit pension plans, which would likely be far higher than the normal ongoing funding cost of the plans. Our operations and financial condition may be adversely affected to the extent that we are required to (i) make any additional payments to any relevant defined benefit pension plans in excess of the amounts assumed in our current projections and assumptions or (ii) report higher pension plan expenses under relevant accounting rules.

We are subject to work stoppages, union negotiations, labor disputes and other matters associated with our labor force, which may adversely impact our operations and cause us to incur incremental costs.

As of January 1, 2023, we had approximately 7,000 employees located around the world consisting of commercial, supply chain, quality, regulatory and compliance, R&D and general administrative personnel. Approximately 15% of our employees globally are covered by a union, collective bargaining agreement or works council. Historically, we have not experienced work stoppages; however, in the future, we may be subject to potential union campaigns, work stoppages, union negotiations and other potential labor disputes. Additionally, future negotiations with unions or works councils in connection with existing labor agreements may (i) result in significant increases in our cost of labor, (ii) divert management's attention away from operating our business or (iii) break down and result in the disruption of our operations. The occurrence of any of the preceding outcomes could impair our ability to manufacture our products and result in increased costs and/or decreased operating results. Further, we may be subject to work stoppages at our suppliers or customers that are beyond our control.

General Risk Factors

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. We may become subject to more proceedings as we expand our business, suppliers, customers and markets. Litigation related to the Company, our business and our operations or financial performance may also involve customers, competitors, suppliers, patients, stockholders, 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 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, property, business interruption and cybersecurity 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, or our insurance coverage may not be sufficient to offset the costs of any losses, lost sales or increased costs experienced during business interruptions. For some risks, we may not obtain insurance if we believe the cost of available insurance is excessive related to the risks presented. Due to market conditions, premiums and deductibles for certain insurance policies can increase substantially and, in some instances, certain insurance policies may become unavailable or available only for reduced amounts of coverage. Further, 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. As a result, we may not be able to renew our insurance policies or procure other desirable insurance on commercially reasonable terms, if at all. Losses and liabilities from uninsured or underinsured events and delay in the payment of insurance proceeds could have a material adverse effect on our financial condition and results of operations.

Some provisions of our Charter, our Bylaws 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 Charter 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 Charter 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 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.

Our Bylaws designate the Court of Chancery of the State of Delaware (the "Court of Chancery") as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Bylaws provides that, unless we consent in writing to the selection of an alternative forum, (i) the Court of Chancery (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for any claims (other than any cause of action arising under the Securities Act), including claims in the right of the Company that are based on a violation of duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, and (ii) the federal district courts of the U.S. will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for any cause of action arising under the Securities Act, but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock will be deemed to have notice of, and to have consented to, the provisions of our Bylaws described in the preceding sentence. This forum selection provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons and result in increased costs for a stockholder to bring a claim. There is uncertainty as to whether a court would enforce such provisions and stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Expectations of our performance related to ESG matters, or the reporting of such matters, may impose additional costs on us and expose us to new risks.

There is an increasing focus and scrutiny from certain investors, customers, vendors, employees and other stakeholders concerning corporate responsibility, specifically related to ESG factors. In addition, government organizations are enhancing or advancing legal and regulatory requirements, including disclosure requirements, specific to ESG matters. 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 must be continuously monitored and 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 few 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 that 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, we may not realize the anticipated benefits of implementing such ESG initiatives and our reputation, business, stock price, financial condition or results of operation could be adversely impacted.

The market price of our common stock may be volatile.

The market price of our common stock may be volatile. Broad general economic, political, market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance and the success of the integration of Quidel and Ortho. Factors that could cause fluctuations in the price of our common stock include:

- global macroeconomic, geopolitical or market conditions;
- actual or anticipated variations in quarterly operating results and the results of competitors;
- changes in financial projections by us, if any, or by any securities analysts that may cover our shares;
- conditions or trends in the industry, including regulatory changes or changes in the securities marketplace;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- our inability to execute on our stock repurchase program as planned, including failure to meet internal or external expectations around the timing or price of stock repurchases, and any reductions or discontinuances of repurchases thereunder;
- additions or departures of key personnel; and
- issuances or sales of our common stock, including sales of common stock by our directors and officers or our significant investors.

Future sales of our common stock by us or our stockholders in the public market, or the perception that such sales may occur, could reduce the price of our common stock, and any additional capital raised by us through the sale of equity or convertible securities may dilute ownership in the Company.

The sale of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

All of our issued shares of common stock are freely tradable without restriction or further registration under the Securities Act, except for any shares held by our affiliates, as that term is defined under Rule 144 of the Securities Act ("Rule 144"), including certain of our directors, executive officers and other affiliates, which shares may be sold in the public market only if they are registered under the Securities Act or are sold pursuant to an exemption from registration such as Rule 144. Shares of our common stock covered by registration rights represent approximately 19% of our outstanding shares as of January 1, 2023. Registration of any of these outstanding shares of common stock would result in such shares becoming freely tradable without compliance with Rule 144 upon effectiveness of the registration statement. As restrictions on resale end or if these stockholders exercise their registration rights, the market price of our common stock could drop significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of common stock or other securities.

In addition, we filed a registration statement with the SEC on Form S-8 providing for the registration of approximately 5.5 million shares of common stock issued or available for issuance under the QuidelOrtho Amended and Restated 2018 Equity Incentive Plan (the "2018 Plan") and the QuidelOrtho Amended and Restated 1983 Employee Stock Purchase Plan (the "ESPP"). Subject to the satisfaction of vesting conditions, shares of common stock registered under the registration statement on Form S-8 may be made available for resale immediately in the public market without restriction.

In the future, we may also issue our securities in connection with investments or acquisitions, or otherwise. We cannot predict the size of future issuances of shares of our common stock or securities convertible into shares of our common stock or the effect, if any, that future issuances and sales of shares of our common stock will have on the market price of our common stock. Sales of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may adversely affect prevailing market prices of our common stock.

If we fail to develop or maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our common stock.

Effective internal controls are necessary for us to provide reliable financial reports, prevent fraud and operate successfully as a public company. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results would be harmed. We cannot be certain that our efforts to develop and maintain an effective system of internal controls will be successful, that we will be able to maintain adequate controls over our financial processes and reporting in the future, or that we will be able to comply with our obligations under Section 404 of the Sarbanes-Oxley Act of 2002. Any failure to develop or maintain effective internal controls, including due to the Combinations or otherwise, or difficulties encountered in implementing or improving internal controls, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which would likely have a negative effect on the trading price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

At January 1, 2023, our material operating locations, which we define as the facilities we lease with more than 75,000 square feet plus all owned facilities of more than 20,000 square feet, were as follows:

Location	Status	Lease Term	Square Footage	Primary Use
Raritan, NJ	Owned	N/A	569,000	Administrative offices, R&D and manufacturing
Rochester, NY (513 Technology Blvd)	Owned	N/A	438,628	Manufacturing
San Diego, CA (Summers Ridge)	Leased	2033 - options to extend for two additional 5-year periods	316,531	Administrative offices, sales and marketing, R&D and manufacturing (principal executive offices)
Rochester, NY (100 Indigo Creek)	Owned	N/A	260,221	Office, R&D
Pencoed, Wales	Owned	N/A	198,380	Office, manufacturing
Athens, OH	Leased	2027	132,993	Administrative offices, sales and marketing, R&D and manufacturing
Carlsbad, CA (Rutherford)	Leased	2036 - options to extend for two additional 5-year periods	128,745	Manufacturing
Memphis, TN	Leased	2026	116,500	Warehouse
San Diego, CA (Waples Ct.)	Leased	2031 - options to extend for two additional 5-year periods	106,412	Office, light manufacturing, storage, packaging, assembly and distribution
Rochester, NY (130 Indigo Creek)	Owned	N/A	103,138	Office, R&D
Strasbourg, France	Owned	N/A	97,951	Warehouse, service
Ibaraki, Japan	Leased	2023	92,988	Land
Rochester, NY (1000 Lee Road)	Leased	2024	89,114	Manufacturing
San Diego, CA (McKellar)	Owned	N/A	72,863	Administrative offices, R&D and manufacturing
Pompano Beach, FL	Owned	N/A	21,500	Manufacturing

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 12 to the Consolidated Financial Statements 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 Select Market under the symbol "QDEL."

As of February 10, 2023, we had approximately 69 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 January 1, 2023:

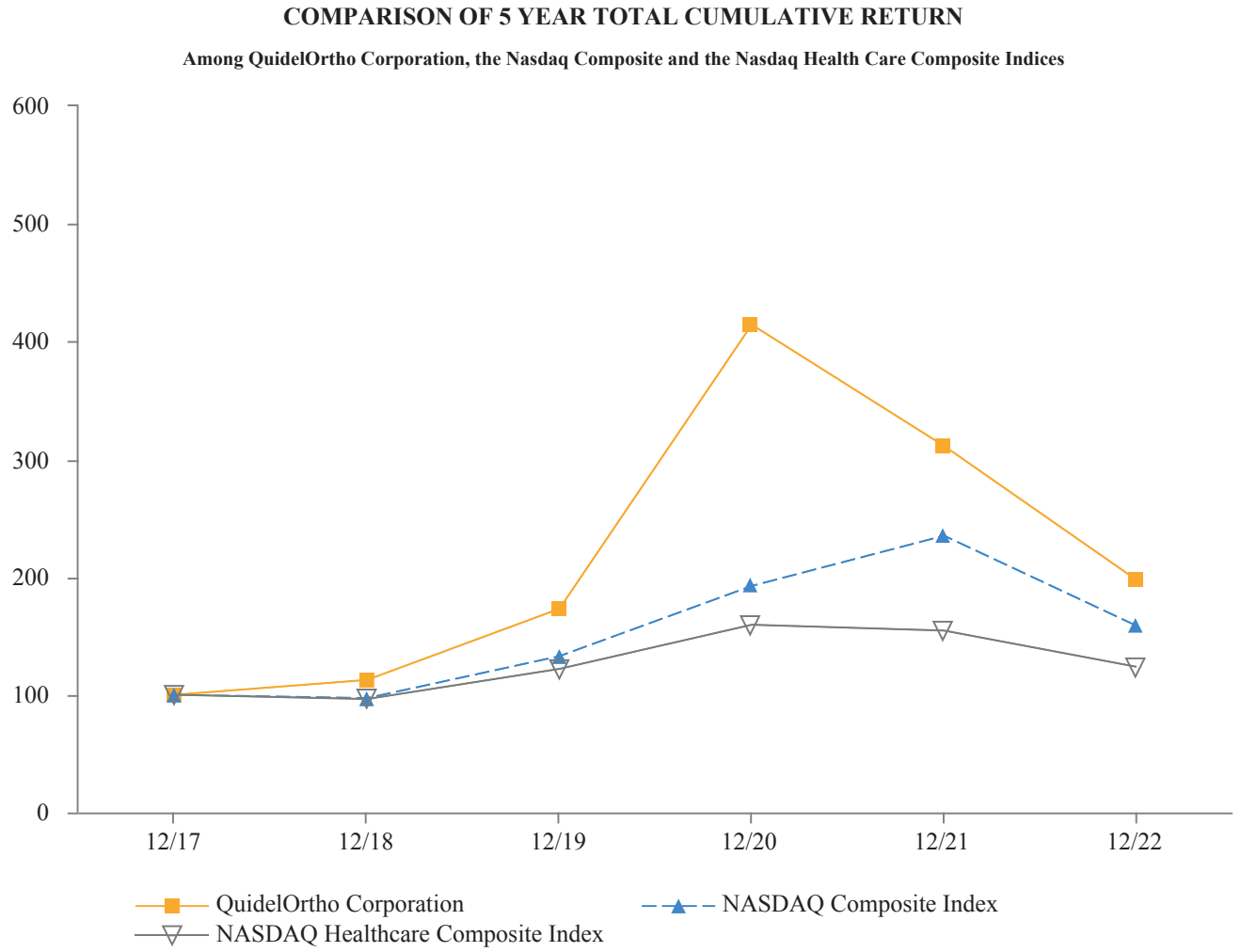
Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (2)
October 3, 2022 - October 30, 2022	931	$ 78.45	—	$ 225,677,460
October 31, 2022 - November 27, 2022	4,632	88.23	—	225,677,460
November 28, 2022 - January 1, 2023	1,103	89.99	—	225,677,460
Total	6,666	$ 87.16	—	$ 225,677,460

(1) Includes shares surrendered, if any, to the Company to satisfy the payment of minimum tax withholding obligations.

(2) On December 18, 2018, Quidel announced a stock repurchase program to repurchase up to $50.0 million of its common stock, which was authorized by Quidel's board of directors (the "Quidel Board") on December 12, 2018. On August 28, 2020, the Quidel Board authorized an increase of an additional $150.0 million to Quidel's existing stock repurchase program authorization, which was announced on September 1, 2020. The Quidel Board also extended the stock repurchase program through August 28, 2022. In connection with the consummation of the Combinations, Quidel's $150.0 million stock repurchase program was terminated. On August 17, 2022, the Board authorized a stock repurchase program, allowing the Company to repurchase up to $300.0 million of its common stock through August 17, 2024.

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 returns of the Nasdaq Composite Index and Nasdaq Health Care Index for the five years ended January 1, 2023. The graph assumes (i) an initial investment of $100 as of the market close on December 29, 2017 in our common stock, the Nasdaq Composite Index and the Nasdaq Health Care Index and (ii) reinvestment of dividends. The graph represents stock price performance of Quidel, from fiscal year 2018 through May 27, 2022, and QuidelOrtho following the closing date of the Combinations. The stock price performance of our common stock depicted in the graph represents past performance only and is not necessarily indicative of future performance.



	Base Period					
Company/Index	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
QuidelOrtho Corporation	**$ 100.00**	$ 112.62	$ 173.08	$ 414.42	$ 311.40	$ 197.62
Nasdaq Composite Index	**$ 100.00**	$ 97.16	$ 132.81	$ 192.47	$ 235.15	$ 158.65
Nasdaq Health Care Composite Index	**$ 100.00**	$ 96.37	$ 121.99	$ 159.49	$ 154.53	$ 123.77

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 Private Securities Litigation Reform Act of 1995 and involve material risks and uncertainties. This discussion should be read in conjunction with the section entitled "Future Uncertainties and Forward-Looking Statements" on page 4 and the "Risk Factors" starting on page 26 of this Annual Report. In addition, our discussion of QuidelOrtho's financial condition

and results of operations in this Item 7 should be read in conjunction with our Consolidated Financial Statements and the related Notes included elsewhere in this Annual Report.

Overview

Our mission is to develop and manufacture intelligent diagnostic solutions that transform the power of diagnostics into a healthier future for everyone. Our expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine helps clinicians and patients make better informed decisions across the globe. Our global infrastructure and commercial reach support our customers across more than 130 countries and territories with quality diagnostics, a broad test portfolio and market-leading service. We operate globally with manufacturing facilities in the U.S. and U.K. and with sales centers, administrative offices and warehouses located throughout the world.

We currently sell our products directly to end users through a direct sales force and through a network of distributors, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other POC settings, blood banks and donor centers, as well as for individual, non-professional, OTC use. We reached significant new markets as we introduced our QuickVue At-Home OTC COVID-19 test for at-home consumer use, school districts, health departments and many other locations.

Beginning in the second quarter of 2022, in connection with the Combinations and in order to manage our business to better align with the market dynamics of the specific geographic regions in which we operate, we changed the manner in which we review our performance and allocate resources. As a result, we changed from one reportable segment to the following three geographically-based reportable segments: North America; EMEA; and China. Latin America, Japan and Asia Pacific are immaterial operating segments that are not considered reportable segments and are included in "Other." We generate our revenue primarily in the following business units: Labs, Transfusion Medicine, Point of Care and Molecular Diagnostics.

For fiscal year 2022, Total revenues increased by 92% to $3,266.0 million as compared to the prior year. Currency exchange rates had an unfavorable impact of 300 basis points on our growth rate. For fiscal year 2021, Total revenues increased by 2% to $1,698.6 million as compared to the prior year. Currency exchange rates had a minimal impact on the growth rate. Our revenues can be highly concentrated over a small number of products. For fiscal years 2022, 2021 and 2020, sales of our COVID-19 products accounted for approximately 44%, 75% and 70% of our Total revenues, respectively. For fiscal years 2022, 2021 and 2020, sales of our influenza products accounted for 11%, 4% and 8% of our Total revenues, respectively. Two of our customers, including one of our distributors, exceeded 10% of our Total revenues for fiscal year 2022. In fiscal year 2021, one distributor exceeded 10% of our Total revenues. In fiscal year 2020, four of our distributors exceeded 10% of our Total revenues.

Recent Developments

On May 27, 2022, pursuant to the BCA, Quidel and Ortho consummated the Combinations and each of Quidel and Ortho became a wholly owned subsidiary of QuidelOrtho. For additional information about the Combinations, see Note 1 under the section "Organization and Business" and Note 2 under the section "Business Combination" to the Consolidated Financial Statements.

The Combinations were completed for total consideration of approximately $4.3 billion (which is based on the May 26, 2022 closing price of $99.60 per share of Quidel common stock), including $1.7 billion of cash, funded through cash on our balance sheet and incremental borrowings. The Combinations have been accounted for as a business combination using the acquisition method of accounting in conformity with Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*.

Commencing from the closing date of the Combinations, our financial statements include the assets, liabilities, operating results and cash flows of Ortho. The revenues related to Ortho are included in the Labs and Transfusion Medicine business units and the results of operations are included within each of our reportable segments, as described in Note 5 to the Consolidated Financial Statements.

Impact of the COVID-19 Pandemic

The healthcare challenge and other impacts surrounding the SARS-CoV-2 virus that emerged in late 2019 and the ensuing global pandemic have presented significant business uncertainty and had a dramatic impact on businesses globally, including ours. As the COVID-19 pandemic reaches an endemic state, the degree to which it continues to impact our business operations, strategy, financial condition and results of operations will depend on future developments that are uncertain and difficult to predict. Although COVID-19 infection rates and severity have decreased recently, the occurrence, spread, severity and duration of any new outbreaks or resurgences, including the emergence and spread of new variants of COVID-19, actions taken to contain the resurgences or variants, and economic repercussions of the virus remain uncertain. We continue to evaluate the nature and extent to which COVID-19 may impact our business and operations and adjust risk mitigation planning and business continuity activities as needed.

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 have and continue to 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, including resurgences and variants. In particular, we developed molecular and antigen products to diagnose the SARS-CoV-2 virus. We also committed significant resources toward the expansion of our production capacity to manufacture and supply these products. We have experienced significant volatility in demand for these products since their launch, with periods of significant demand and periods where we experienced dramatic decreases in demand. At the same time, we also have observed fluctuating demand for certain of our other diagnostic products. Demand for our products to identify the SARS-CoV-2 virus has fluctuated in line with a range of factors, including the prevalence of the SARS-CoV-2 virus and its variants, the supply of COVID-19 tests generally, the purchasing activity of government entities, and the dissemination and effectiveness of vaccinations. The extent to which COVID-19 will continue to impact demand for our products depends on these and future developments, which are highly uncertain and difficult to predict, including new information that may emerge concerning the severity of COVID-19 resurgences, regulatory changes in any of the markets in which we serve, the impact of new SARS-CoV-2 variants and actions to contain and treat their impact.

Operations and Employee Safety

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. However, pandemic-related lockdowns and other responses to the pandemic in a number of countries have adversely impacted, and for some continue to adversely impact, our business operations in those countries. For example, lockdowns in China have impacted our business operations in that country. The adverse impacts of these measures were not material to our results of operations for the fiscal year ended January 1, 2023. We continue to monitor potential further impacts from these measures and the other issues noted above regarding our business.

As a result of the COVID-19 pandemic, we have implemented steps to protect our employees. Our office-based work sites in the U.S. are subject to operating restrictions consistent with applicable health guidelines.

Supply Chains

As a result of the COVID-19 pandemic and other macroeconomic and geopolitical conditions, including inflationary pressures, general economic slowdown or a recession, rising interest rates, foreign exchange rate volatility and changes in monetary policy, we have experienced shortages and delays in receiving certain raw materials and other components for our products and have experienced logistics and distribution challenges, as well as challenges in labor availability and rising labor costs, all of which have affected our ability to fulfill customer orders, including instrument placements, on a timely basis. Supply chain, production, logistics and distribution challenges, including shortages of raw materials and components, cost inflation, shipping delays, labor availability constraints and rising labor costs, have impacted, and we expect will continue for some period of time to impact, our results of operations.

Some of our raw materials are available from a limited number of sources. During 2022, we encountered some increasing pressures on raw material pricing. To mitigate these supply chain challenges, we are (i) partnering with suppliers to invest in additional capacity and raw material inventory, (ii) diversifying our supply base, where possible, to minimize reliance on a single source of supply for key raw materials and components and (iii) creating redundancy in our global supply chain. In addition, we routinely evaluate our supply chain for potential gaps and continue to take other steps intended to help address continuity. In our distribution operations, we are investing in automation capabilities to help improve accuracy and timeliness of customer shipments.

We continue to monitor these developments, as well as other international developments, including the Russia-Ukraine conflict, rising tensions between China and Taiwan and localization efforts, and the impact of such factors on our business. We cannot currently predict the frequency, duration or scope of these supply, production, logistics, distribution and labor disruptions and challenges. However, we proactively work with our suppliers, manufacturers, distributors, industry partners and government agencies to address these challenges in our efforts to meet the needs of our customers. Despite our mitigation efforts, such disruptions and challenges have and could further 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 challenges.

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 occurrence, spread, severity and duration of any new outbreaks and resurgences of COVID-19, the emergence and spread of new variants of COVID-19, and the ongoing supply, production and logistics challenges.

Demand for our COVID-19 testing products declined in the second half of 2022 compared to both the first half of 2022 and the second half of 2021, which may indicate the beginning of a transition to an endemic environment. For 2023, we expect demand for our COVID-19 testing products to fluctuate and pricing pressures to continue as a result of a number of factors, including increased supply, emergence and spread of new variants, effectiveness of global containment efforts and other mitigation efforts. However, in light of our experience to date with the virus and the emergence and impact of new variants, we believe some level of COVID-19 testing may continue for some period of time, even as communities return to more normal practices. We would expect any such normalized demand to continue to experience fluctuations, which may be significant. With respect to our core products, excluding respiratory products, we anticipate revenue growth for 2023.

Because our business environment is highly competitive, our long-term growth and profitability will depend in part on our ability to retain and grow our current customers and attract new customers through developing and delivering new and improved products and services that meet our customers' needs and expectations, including with respect to product performance, product offerings, cost, automation and other work-flow efficiency. As a result, we expect to continue to maintain our emphasis on R&D investments for longer term growth, including for our next generation platforms and assays, as well as additional assays to be launched on our current platforms. In addition, we expect to continue to evaluate strategic opportunities to expand our product lines and services, production capabilities, technologies and geographic footprint and address other business challenges and opportunities.

While the revenues and financial results from our COVID-19 products are uncertain, 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 and services into the market.

Results of Operations

Comparison of fiscal years ended 2022, 2021 and 2020

Our fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. Fiscal years 2022 and 2021 were 52 weeks and fiscal year 2020 was 53 weeks.

Revenues

The following table compares Total revenues by business unit for fiscal years 2022, 2021 and 2020:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Labs	$ 820.2	$ 44.8	$ 50.9	1,731 %	(12)%
Transfusion Medicine	393.8	—	—	N/A	N/A
Point of Care	1,955.3	1,453.3	1,387.8	35 %	5 %
Molecular Diagnostics	96.7	200.5	223.0	(52)%	(10)%
Total revenues	$ 3,266.0	$ 1,698.6	$ 1,661.7	92 %	2 %

For fiscal year 2022, Total revenues increased to $3,266.0 million from $1,698.6 million for the prior year. The increases in Labs and Transfusion Medicine were primarily related to new revenues from the Combinations. The Point of Care business unit contributed to revenue growth, driven primarily by an increase of $586.1 million in sales of QuickVue SARS Antigen assays, partially offset by lower sales of Sofia assays and $46.7 million lower BNP sales due to the transition of the BNP Business to Beckman. The decrease in revenues related to the transition of the BNP Business did not materially impact our gross profit. Molecular Diagnostics sales decreased by $103.8 million, driven primarily by lower demand and pricing of the Lyra SARS Antigen assay. Currency exchange rate had an unfavorable impact of approximately 300 basis points on the growth rate for fiscal year 2022.

For fiscal year 2021, Total revenues increased to $1,698.6 million from $1,661.7 million for the prior year. The Point of Care business unit was the largest contributor to revenue growth, driven by sales of the QuickVue SARS Antigen assay. Additionally, sales of our other products within our Point of Care business unit increased 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. Molecular Diagnostics sales decreased by $22.5 million, 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 Labs 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. Favorable currency exchange rate impact for fiscal year 2021 had a minimal impact on the growth rate.

Cost of Sales, Excluding Amortization of Intangible Assets

Cost of sales, excluding amortization of intangible assets, increased to $1,330.0 million, or 40.7% of Total revenues, for fiscal year 2022, compared to $420.3 million, or 24.7% of Total revenues, for fiscal year 2021. The increase in cost of sales, excluding amortization of intangible assets, was driven primarily by a large increase in sales of QuickVue SARS Antigen assays in 2022, as well as new product sales in the Labs and Transfusion Medicine business units as a result of the Combinations. We also recorded $60.6 million of expense related to the amortization of the inventory fair value adjustment related to the Combinations during fiscal year 2022. There were also increases in supply chain and other indirect manufacturing costs, which were only partially offset by increased absorption driven by higher production volumes.

Cost of sales, excluding amortization of intangible assets, increased to $420.3 million, or 24.7% of Total revenues, for fiscal year 2021, compared to $305.4 million, or 18.4% of Total revenues, for fiscal year 2020. The increase in cost of sales, excluding amortization of intangible assets, was driven primarily by a shift in product mix from Sofia SARS products to QuickVue SARS products and lower selling prices for our SARS products in fiscal year 2021. Increases in supply chain and other indirect manufacturing costs were more than offset by increased absorption driven by higher production volumes.

Operating Expenses

The following table summarizes operating expenses for fiscal years 2022, 2021 and 2020:

	Fiscal Year Ended					
(Dollars in millions)	2022	% of Total Revenues	2021	% of Total Revenues	2020	% of Total Revenues
Selling, marketing and administrative	$ 621.0	19.0 %	$ 239.6	14.1 %	$ 180.7	10.9 %
Research and development	190.5	5.8 %	95.7	5.6 %	84.3	5.1 %
Amortization of intangible assets	132.5	4.1 %	27.4	1.6 %	27.3	1.6 %
Acquisition and integration costs	136.0	4.2 %	9.6	0.6 %	3.7	0.2 %
Other operating expense, net	12.3	0.4 %	—	— %	—	— %

Selling, Marketing and Administrative Expenses

Selling, marketing and administrative expenses for fiscal year 2022 increased by $381.4 million, or 159.2%, to $621.0 million from $239.6 million for the prior year, driven primarily by the Combinations which contributed $326.5 million in increased expense, freight expense due to higher sales volume and expedited shipping, product promotional spend associated with the QuickVue At-Home OTC COVID-19 test, professional fees and employee-related costs.

Selling, marketing and administrative expenses for fiscal year 2021 increased by $58.9 million, or 32.6%, to $239.6 million from $180.7 million for the prior year, driven primarily by higher 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. The increase was also related to higher compensation costs from increased headcount to support the growth of the business experienced during fiscal year 2021, and higher charitable contributions and stock compensation expense.

Research and Development Expense

Research and development expense for fiscal year 2022 increased by $94.8 million, or 99.1%, to $190.5 million from $95.7 million for the prior year, primarily due to the Combinations which contributed $86.0 million in increased expense, as well as increased costs related to SARS, Sofia and Savanna projects, and increased costs related to compensation driven by increased headcount and clinical trials.

Research and development expense for fiscal year 2021 increased by $11.4 million, or 13.5%, to $95.7 million from $84.3 million for the prior year, primarily due to increased costs related to the Savanna and QuickVue OTC projects, partially offset by decreased spending on Sofia projects. We also incurred higher labor, materials and clinical trials costs as a result of the COVID-19 product development.

Amortization of Intangible Assets

Amortization of intangible assets for fiscal years 2022, 2021 and 2020 was $132.5 million, $27.4 million and $27.3 million, respectively. The increase in amortization expense in fiscal year 2022 compared to the prior year periods was primarily due to the Combinations.

Acquisition and Integration Costs

Acquisition and integration costs were $136.0 million, $9.6 million and $3.7 million for fiscal years 2022, 2021 and 2020, respectively. The increase in costs in fiscal year 2022 was primarily due to transaction and integration-related costs attributable to the Combinations. Costs in the prior year periods were primarily related to the evaluation of new business development opportunities, including the Combinations.

Other Operating Expense, Net

Other operating expense, net was $12.3 million for fiscal year 2022, which was related to the profit share expense for our Joint Business with Grifols acquired in connection with the Combinations.

Non-operating Expenses

The following table summarizes non-operating expenses, net for fiscal years 2022, 2021 and 2020:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Interest expense, net	$ 75.7	$ 5.8	$ 8.5	N/M	(31.8)%
Loss on extinguishment of debt	24.0	—	10.4	N/M	(100.0)%
Other expense (income), net	8.1	(0.1)	1.1	N/M	N/M

* N/M - Not meaningful

Interest Expense, Net

Interest expense, net was $75.7 million, $5.8 million and $8.5 million for fiscal years 2022, 2021 and 2020, respectively. The increase in interest expense, net in fiscal year 2022 compared to the prior year periods was primarily related to the new Term Loan under the Credit Agreement entered into in connection with the Combinations. See Note 8 to the Consolidated Financial Statements for more information related to our Term Loan.

Interest expense, net prior to the Combinations primarily related 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 fiscal year 2020) and interest and amortization of deferred financing costs associated with our previous credit agreement. Interest expense, net for fiscal year 2021 decreased to $5.8 million from $8.5 million for the prior year. The decrease compared to the prior year was primarily due to the maturity of our Convertible Notes in December 2020 and lower deferred consideration liability outstanding during fiscal year 2021.

Loss on Extinguishment of Debt

Loss on extinguishment of debt was $24.0 million for fiscal year 2022, and was related to the extinguishment of the senior notes and former term loans and the revolving credit facility of Ortho in connection with the Combinations.

Loss on extinguishment of debt was $10.4 million for fiscal year 2020, and was 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.

Other Expense (Income), Net

Other expense (income), net was $8.1 million, $(0.1) million and $1.1 million for fiscal years 2022, 2021 and 2020, respectively. Other expense, net in fiscal year 2022 compared to income in fiscal year 2021 was primarily related to net foreign currency losses and loss on investment, partially offset by fair value gains in interest rate caps. Other expense, net during fiscal year 2020 was primarily related to an unfavorable change in fair value of derivative liabilities associated with the Convertible Notes conversion in fiscal year 2020.

Income Taxes

For fiscal years 2022 and 2021, we recognized income tax provisions of $187.2 million in relation to income before taxes of $735.9 million, and $196.1 million in relation to income before taxes of $900.3 million, respectively, resulting in effective tax rates of 25.4% and 21.8%, respectively. The lower tax expense for fiscal year 2022 compared to the prior year was primarily due to a decrease in pre-tax profits and state taxes, foreign income taxed at rates other than the applicable U.S. rate, and an increased deduction for foreign derived intangible income (FDII), partially offset by increases in non-deductible executive compensation, Global Intangible Low-Taxed Income and acquisition-related costs.

We recognized an income tax provision of $196.1 million, resulting in an effective tax rate of 21.8% for fiscal year 2021. This effective tax rate is comparable to the effective tax rate of 22.1% for fiscal year 2020. In both years, the effective tax rate differed 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.

Indemnification Assets

On January 16, 2014, Ortho entered into a stock and asset purchase agreement of (i) certain assets and liabilities and (ii) all of the equity interests and substantially all of the assets and liabilities of certain entities, which, together with their subsidiaries, comprised the Ortho business from Johnson & Johnson. The agreement generally provided that Johnson & Johnson retained all income tax liabilities accrued as of the date of the acquisition, including reserves for unrecognized tax benefits. The indemnification receivable from Johnson & Johnson totaled $16.8 million as of January 1, 2023 and is included as a component of Prepaid expenses and other current assets and Other assets on the Consolidated Balance Sheet. We recorded $0.4 million of interest and penalties during fiscal year 2022.

Segment Results

In the quarter ended July 3, 2022, following the completion of the Combinations, we changed the manner in which we evaluate performance and allocate resources. As a result, we began to operate under three geographically-based reportable segments: North America; EMEA; and China. Our operations in Latin America, Japan and Asia Pacific are immaterial operating segments that are not considered reportable segments and are included in "Other." In the fourth quarter of 2022, we revised the internal allocation of certain global costs primarily between the North America segment and Corporate to better align costs that impact us as a whole. Prior periods have been revised to align with the current period presentation.

The key indicators that we monitor are as follows:

- Total revenues — This measure is discussed in the section entitled "Results of Operations."
- Adjusted EBITDA — Adjusted EBITDA by reportable segment is used by our management to measure and evaluate the internal operating performance of our reportable segments. It is also the basis for calculating certain management incentive compensation programs. We believe that this measurement is useful to investors as a way to analyze the underlying trends in our core business, including at the segment level, consistently across the periods presented and to evaluate performance under management incentive compensation programs. Adjusted EBITDA consists of Net income before Interest expense, net, Provision for (benefit from) income taxes and depreciation and amortization and eliminates (i) certain non-operating income or expense items, and (ii) impacts of certain noncash, unusual or other items that are included in net income and that we do not consider indicative of our ongoing operating performance. See Note 5 to the Consolidated Financial Statements for a reconciliation of Adjusted EBITDA by reportable segment to Income before provision for income taxes.

North America

Total revenues and Adjusted EBITDA for North America were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Total revenues	$ 2,536.5	$ 1,500.2	$ 1,460.7	69 %	3 %
Adjusted EBITDA	$ 1,614.6	$ 1,028.5	$ 1,205.2	57 %	(15)%

Total revenues were $2,536.5 million for fiscal year 2022, compared to Total revenues of $1,500.2 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $607.3 million to Total revenues. The remaining increase of $429.0 million was driven primarily by increased demand for the QuickVue SARS Antigen assays and non-SARS related rapid tests, partially offset by a decrease in revenues for the Sofia SARS Antigen assay.

Total revenues were $1,500.2 million for fiscal year 2021, compared to Total revenues of $1,460.7 million for fiscal year 2020. The increase of $39.5 million was driven primarily by increased demand for the QuickVue SARS Antigen assays, offset by a decrease in revenues for the Sofia SARS Antigen assay.

Adjusted EBITDA was $1,614.6 million for fiscal year 2022, compared to Adjusted EBITDA of $1,028.5 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $260.7 million to Adjusted EBITDA. The remaining increase of $325.4 million was driven primarily by increased revenues, partially offset by increased distribution and selling costs.

Adjusted EBITDA was $1,028.5 million for fiscal year 2021, compared to Adjusted EBITDA of $1,205.2 million for fiscal year 2020. The decrease of $176.7 million was driven primarily by increased distribution and selling costs.

EMEA

Total revenues and Adjusted EBITDA for EMEA were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Total revenues	$ 206.8	$ 69.6	$ 92.9	197 %	(25)%
Adjusted EBITDA	$ 31.7	$ 28.1	$ 55.5	13 %	(49)%

Total revenues were $206.8 million for fiscal year 2022, compared to Total revenues of $69.6 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $146.2 million to Total revenues. The remaining decrease of $9.0 million was primarily driven by lower Point of Care revenues due to lower BNP sales from the transition of the BNP Business to Beckman.

Total revenues were $69.6 million for fiscal year 2021, compared to Total revenues of $92.9 million for fiscal year 2020. During fiscal year 2021, Total revenues decreased by $23.3 million, primarily due to lower Molecular Diagnostics and Point of Care revenues, driven by lower Lyra SARS Antigen assay sales.

Adjusted EBITDA was $31.7 million for fiscal year 2022, compared to Adjusted EBITDA of $28.1 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $18.1 million to Adjusted EBITDA. The remaining decrease of $14.5 million was driven primarily by lower revenues and increased selling costs.

Adjusted EBITDA was $28.1 million for fiscal year 2021, compared to Adjusted EBITDA of $55.5 million for fiscal year 2020. During fiscal year 2021, Adjusted EBITDA decreased $27.4 million, driven primarily by lower revenues.

China

Total revenues and Adjusted EBITDA for China were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Total revenues	$ 220.0	$ 58.0	$ 62.4	279 %	(7)%
Adjusted EBITDA	$ 104.1	$ 24.1	$ 30.5	332 %	(21)%

Total revenues were $220.0 million for fiscal year 2022, compared to Total revenues of $58.0 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $161.3 million to Total revenues. The remaining increase of $0.7 million was primarily driven by increased Point of Care revenues, partially offset by lower BNP sales due to the transition of the BNP Business to Beckman.

Total revenues were $58.0 million for fiscal year 2021, compared to Total revenues of $62.4 million for fiscal year 2020. The decrease of $4.4 million was primarily due to decreased Point of Care revenues, driven by lower BNP sales due to the transition of the BNP Business to Beckman.

Adjusted EBITDA was $104.1 million for fiscal year 2022, compared to Adjusted EBITDA of $24.1 million for fiscal year 2021. During fiscal year 2022, the Combinations were the primary driver of the increase, which contributed $80.7 million to Adjusted EBITDA.

Adjusted EBITDA was $24.1 million for fiscal year 2021, compared to Adjusted EBITDA of $30.5 million for fiscal year 2020. During fiscal year 2021, Adjusted EBITDA decreased $6.4 million, driven primarily by lower revenues.

Other

Total revenues and Adjusted EBITDA for Other, which includes our Latin America, Japan and Asia Pacific operating segments, were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2022	2021	2020	% Change 2022 vs. 2021	% Change 2021 vs. 2020
Total revenues	$ 302.7	$ 70.8	$ 45.7	328 %	55 %
Adjusted EBITDA	$ 92.7	$ 43.0	$ 28.0	116 %	54 %

Total revenues were $302.7 million for fiscal year 2022, compared to Total revenues of $70.8 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $250.5 million to Total revenues. The remaining decrease of $18.6 million was primarily due to lower Point of Care revenues, driven primarily by lower demand for QuickVue SARS Antigen and Sofia assays.

Total revenues were $70.8 million for fiscal year 2021, compared to Total revenues of $45.7 million for fiscal year 2020. During fiscal year 2021, Total revenues increased $25.1 million, primarily due to higher Point of Care revenues, driven by higher demand for QuickVue SARS Antigen and Sofia assays.

Adjusted EBITDA was $92.7 million for fiscal year 2022, compared to Adjusted EBITDA of $43.0 million for fiscal year 2021. During fiscal year 2022, the impact of the Combinations contributed $62.9 million to Adjusted EBITDA. The remaining decrease of $13.2 million was driven primarily by lower revenues.

Adjusted EBITDA was $43.0 million for fiscal year 2021, compared to Adjusted EBITDA of $28.0 million for fiscal year 2020. During fiscal year 2021, Adjusted EBITDA increased $15.0 million, driven primarily by higher revenues.

Liquidity and Capital Resources

As of January 1, 2023 and January 2, 2022, the principal sources of liquidity consisted of the following:

(Dollars in millions)	January 1, 2023	January 2, 2022
Cash and cash equivalents	$ 292.9	$ 802.8
Marketable securities, current	52.1	25.7
Marketable securities, non-current	21.0	37.9
Total cash, cash equivalents and marketable securities	$ 366.0	$ 866.4
Amount available to borrow under the Revolving Credit Facility	$ 786.9	$ 175.0
Working capital including cash and cash equivalents and marketable securities, current	$ 568.1	$ 1,116.8

As of January 1, 2023, we had $292.9 million in Cash and cash equivalents, a $509.9 million decrease from January 2, 2022. Our cash requirements fluctuate as a result of numerous factors, including cash generated from operations, progress in R&D, capital expansion projects and acquisition and business development activities. On May 27, 2022, we completed the Combinations for total consideration of $4,291.1 million (which is based on the May 26, 2022 closing price of $99.60 per share of Quidel common stock), including $1,747.7 million of cash, net of cash and restricted cash acquired, funded through cash on our balance sheet and incremental borrowings. The incremental borrowings, described below, were also used to repay substantially all of Ortho's then-outstanding indebtedness. We believe our organizational structure allows us the necessary flexibility to move funds throughout our subsidiaries to meet our operational working capital needs.

Debt Capitalization

On May 27, 2022, we entered into the Credit Agreement by and among us, as borrower, Bank of America, as administrative agent and swing line lender, and the other Lenders party thereto. Pursuant to the Credit Agreement and in connection with the consummation of the Combinations, the Lenders provided us with a $2,750.0 million Term Loan and a $750.0 million Revolving Credit Facility. Effective August 4, 2022, pursuant to the Increase Joinder No. 1 to the Credit Agreement, the Revolving Credit Facility was increased by $50.0 million to $800.0 million. The Financing is guaranteed by the Guarantors and is secured by liens on substantially all of our and the Guarantors' assets, excluding real property and certain other types of excluded assets. Loans under the Credit Agreement will bear interest at a rate per annum equal to the Term SOFR or Base Rate plus the Applicable Rate (each as defined in the Credit Agreement). As of January 1, 2023, letters of credit issued under the

Revolving Credit Facility totaled $13.1 million, which reduced the available amount under the Revolving Credit Facility to $786.9 million.

The Term Loan is subject to quarterly amortization of the principal amount on the last business day of each of our fiscal quarters (commencing on September 30, 2022). The required quarterly payments are 1.875% of the aggregate initial principal amount of the Term Loan through the fiscal second quarter of 2024, and 1.250% thereafter. The final remaining principal installment is due on the maturity date. The Term Loan and the Revolving Credit Facility will mature on May 27, 2027. We must prepay loans outstanding under the Credit Agreement in an amount equal to the Net Cash Proceeds from (i) certain property dispositions and (ii) the receipt of certain other amounts not in the ordinary course of business, such as certain insurance proceeds and condemnation awards, in each case, if not reinvested within a specified time period as contemplated in the Credit Agreement.

The Credit Agreement 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, investments and transactions with affiliates. The Credit Agreement contains two financial covenants: (i) a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) as of the last day of each fiscal quarter of (a) 4.50 to 1.00 for the Initial Measurement Period, (b) 4.00 to 1.00 for the first four fiscal quarters ending after the Initial Measurement Period and (c) 3.50 to 1.00 for each fiscal quarter thereafter; and (ii) a minimum Consolidated Interest Coverage Ratio (as defined in the Credit Agreement) of 3.00 to 1.00 as of the end of any fiscal quarter for the most recently completed four fiscal quarters. We were in compliance with the financial covenants as of January 1, 2023.

The Credit Agreement was entered into in connection with the Combinations in order to fund a portion of the cash portion of the purchase price as well as to repay substantially all of Ortho's then-outstanding indebtedness. See Note 2 to the Consolidated Financial Statements for further discussion of the Combinations. In connection with the closing of the Combinations, Quidel terminated its previous $175.0 million revolving credit facility and related credit agreement on May 27, 2022, which did not have an outstanding balance.

In connection with the acquisition of the BNP Business, we had an annual installment payment of $48.0 million payable in 2022 and will have an annual installment payment of $40.0 million payable in 2023. As of January 1, 2023, the remaining payment was recorded at fair value as contingent consideration of $0.1 million and deferred consideration of $39.3 million.

In connection with the Combinations, the Company acquired a receivables purchase agreement (the "RPA"), entered into on June 11, 2021, by and among Ortho-Clinical Diagnostics US FinanceCo I, LLC ("Ortho FinanceCo I"), a wholly owned receivables financing subsidiary of the Company, Wells Fargo Bank, N.A., as administrative agent (the "Agent"), Ortho-Clinical Diagnostics, Inc. ("Ortho," the "Master Servicer"), and certain Purchasers, as amended on July 20, 2022 (the "RPA Amendment"). Under the RPA, Ortho FinanceCo I may sell receivables in amounts up to a $75.0 million limit, subject to certain conditions, including that, at any date of determination, the aggregate capital paid to Ortho FinanceCo I does not exceed a "capital coverage amount," equal to an adjusted net receivables pool balance minus a required reserve. Ortho FinanceCo I has guaranteed the prompt payment of the sold receivables, and to secure the prompt payment and performance of such guaranteed obligations, Ortho FinanceCo I has granted a security interest to the Agent, for the benefit of the Purchasers, in all assets of Ortho FinanceCo I. Ortho, in its capacity as Master Servicer under the RPA, is responsible for administering and collecting the receivables and has made customary representations, warranties, covenants and indemnities. The Company has also provided a performance guaranty for the benefit of Ortho FinanceCo I to cause the due and punctual performance by Ortho of its obligations as Master Servicer. The RPA Amendment resulted in a net 50 basis-point reduction of fees and revision of the base interest rate from 1-month LIBOR to 1-month SOFR.

Stock Repurchases

On August 17, 2022, the Board authorized the Stock Repurchase Program, allowing the Company to repurchase up to $300.0 million of its common stock through August 17, 2024. The Stock Repurchase Program does not obligate the Company to acquire any specific number of shares. Under the Stock Repurchase Program, shares of common stock may be repurchased using a variety of methods, including privately negotiated and/or open market transactions, including under plans complying with Rule 10b5-1 under the Exchange Act, as part of accelerated stock repurchases and other methods. The timing, manner, price and amount of any repurchases are determined by the Company in its discretion and depend on a variety of factors, including legal requirements, price and economic and market conditions. For the fiscal year ended January 1, 2023, the Company repurchased 953,468 shares of outstanding common stock under the Stock Repurchase Program for approximately $74.3 million. The repurchased shares were retired and returned to the status of authorized but unissued shares of our common stock. As of January 1, 2023, we had approximately $225.7 million available under the Stock Repurchase Program.

Cash Flow Summary

(In millions)	Fiscal Year Ended 2022	2021	2020
Net cash provided by operating activities:	$ 885.3	$ 805.9	$ 629.7
Net cash used for investing activities:	(1,644.2)	(319.5)	(63.3)
Net cash provided by (used for) financing activities:	252.0	(173.1)	(130.3)
Effect of exchange rates on cash	(2.0)	(0.4)	1.0
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (508.9)	$ 312.9	$ 437.1

Fiscal Year Ended January 1, 2023

Cash provided by operating activities was $885.3 million for fiscal year 2022, and reflected net income of $548.7 million and non-cash adjustments of $389.8 million, primarily associated with depreciation and amortization, stock-based compensation expense, deferred income taxes, loss on extinguishment of debt and amortization of the inventory fair value step up initially recorded in connection with the Combinations. In addition, we benefited from collections on accounts receivables, which contributed $150.2 million to Cash provided by operating activities, partially offset by net cash outflows related to inventories, prepaid and other current and non-current assets and liabilities as well as income taxes payable and other current and non-current liabilities.

Cash used for investing activities was $1,644.2 million for fiscal year 2022, and was primarily related to the Combinations. We purchased $140.9 million of property, equipment, investments and intangibles and received $18.4 million of proceeds from government assistance allocated to fixed assets. We also purchased $63.7 million and sold $53.4 million of marketable securities during fiscal year 2022. See Note 2 to the Consolidated Financial Statements for further discussion regarding the Combinations.

Cash provided by financing activities was $252.0 million for fiscal year 2022, and was primarily related to proceeds from long-term borrowings, net of debt issuance costs of $2,734.5 million, payments on long-term borrowings and extinguishment costs of $2,388.3 million, repurchases of common stock of $74.3 million and payments of $37.7 million for contingent and deferred consideration.

Fiscal Year Ended January 2, 2022

Cash provided by operating activities was $805.9 million for fiscal year 2021, and reflected net income of $704.2 million and non-cash adjustments of $104.5 million, primarily associated with depreciation and amortization, stock-based compensation expense 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 used for investing activities was $319.5 million for fiscal year 2021, and was primarily related to investments in manufacturing equipment, building improvements, Sofia, Solana and Triage instruments available for lease and 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.

Cash used for financing activities was $173.1 million for fiscal year 2021, and was primarily related to repurchases of common stock of $103.5 million, payments of tax withholdings for vesting of stock-based awards of $37.1 million, and the payment of deferred and contingent consideration of $39.8 million, partially offset by proceeds of $7.6 million from the issuance of common stock under the ESPP and pursuant to stock option exercises.

Fiscal Year Ended January 3, 2021

Cash provided by operating activities was $629.7 million for fiscal year 2020, and reflected net income of $810.3 million and non-cash adjustments of $70.6 million, primarily associated with depreciation and amortization, stock-based compensation expense, 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 $251.2 million primarily driven by increases in accounts receivable and product inventory, partially offset by increases in income taxes payable and accounts payable.

Cash used for investing activities was $63.3 million for fiscal year 2020, and was primarily related to investments in manufacturing equipment, Sofia, Solana and Triage instruments available for lease, building improvements and purchases of scientific equipment.

Cash used for financing activities was $130.3 million for fiscal year 2020, and was primarily related to repurchases of common stock of $43.7 million, payment of Convertible Notes and derivative liability of $43.4 million, payments of 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.

Liquidity Outlook

Short-term Liquidity Outlook

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 anticipate that our current Cash and cash equivalents, together with cash provided by operating activities and amounts available under our Revolving Credit Facility, 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, R&D and capital expenditures. Our primary short-term needs for capital, which are subject to change, include expenditures related to:

- interest on and repayments of our long-term borrowings, deferred consideration, contingent consideration and lease obligations;
- acquisitions of equipment and other fixed assets in support of our manufacturing facility expansion;
- the continued advancement of R&D efforts;
- our integration of the Ortho business arising from the Combinations;
- support of commercialization efforts related to our current and future products, including support of our direct sales force and field support resources; and
- potential strategic acquisitions and investments.

Due to the risks inherent in the product development process, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization. Our R&D costs may be substantial as we move product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

The primary purposes of our capital expenditures are to invest in manufacturing capacity expansion, acquire certain of our instruments, acquire scientific equipment, purchase or develop IT and implement facility improvements. We plan to fund the capital expenditures with the cash on our balance sheet.

We are focused on expanding the number of instruments placed in the field and solidifying long-term contractual relationships with customers. In order to achieve this goal, in certain jurisdictions where it is permitted, we have leveraged a reagent rental model that has been recognized as more attractive to certain customers. In this model, we lease, rather than sell, instruments to our customers. Over the term of the contract, the purchase price of the instrument is embedded in the price of the assays and reagents. Going forward, we intend to increase the number of reagent rental placements in developed markets, a strategy that we believe is beneficial to our commercial goals because it lowers our customers' upfront capital costs and therefore allows purchasing decisions to be made at the lab manager level. For these same reasons, the reagent rental model also benefits our commercial strategy in emerging markets. We believe that the shift in our sales strategy will grow our installed base, thereby increasing sales of higher-margin assays, reagents and other consumables over the life of the customer contracts and enhancing our recurring revenue and cash flows. During fiscal year 2022, we transferred $73.7 million of instrument inventories from Inventories to Property, plant and equipment, net, further increasing our investment in property, plant and equipment.

Long-term Liquidity Outlook

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 successfully integrate the recently acquired Ortho business and realize cross-selling revenue synergies;
- 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.

Contractual Obligations

Principal payments required on our long-term debt outstanding as of January 1, 2023 are $207.5 million in fiscal year 2023, $310.2 million in fiscal years 2024 to 2025 and $2,131.2 million in fiscal years 2026 to 2027. See Note 8 to our Consolidated Financial Statements for further discussion of long-term debt. Interest payments required on long-term debt outstanding as of January 1, 2023 are $172.5 million in fiscal year 2023, $258.1 million in fiscal years 2024 to 2025 and $149.7 million in fiscal years 2026 to 2027. Future interest payments include commitment fees on the unused portion of the Revolving Credit Facility and interest payments on our Term Loan. Future interest payments assume January 1, 2023 interest rates will prevail throughout all periods. Actual interest payment amounts may differ in the future based on changes in market interest rates.

As of January 1, 2023, estimated contractual obligations for operating lease payments were $256.5 million, with $32.7 million due in fiscal year 2023, $55.5 million in fiscal years 2024 to 2025, $45.4 million in fiscal years 2026 to 2027 and $122.9 million in fiscal year 2028 and thereafter. The amounts reflect future minimum lease obligations on facilities and equipment under operating leases in place as of January 1, 2023. See Note 9 to our Consolidated Financial Statements for further discussion of operating leases.

We are committed to making annual deferred and contingent consideration payments related to the acquisition of the BNP Business of up to $48 million. The remaining obligation as of January 1, 2023 was $40 million, which is expected to be paid in fiscal year 2023.

In connection with the Combinations, the Company assumed certain defined benefit plan obligations and acquired related plan assets for employees of non-U.S. subsidiaries. We expect to make contributions of $2.0 million to our defined benefit plans in fiscal year 2023. The amount of any contributions is dependent on the future economic environment and investment returns, and we are unable to reasonably estimate pension contributions beyond fiscal year 2023. See Note 15 to our Consolidated Financial Statements for further discussion of our defined benefit plans.

As of January 1, 2023, we had approximately $247.8 million of purchase obligations, which include agreements to purchase goods or services that are enforceable and legally binding and that specify all significant terms, including (i) fixed or minimum quantities to be purchased, (ii) fixed, minimum or variable price provisions and (iii) the approximate timing of the transaction, as well as amounts for planned inventory purchases under contractual arrangements. We expect the majority of the payments related to these purchase obligations to be made during fiscal year 2023.

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 $1.1 million, $2.0 million and $2.4 million as of January 1, 2023, January 2, 2022 and January 3, 2021, respectively.

As of January 1, 2023, we had approximately $40.0 million of liabilities associated with uncertain tax positions. 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 January 1, 2023. See Note 6 to our Consolidated Financial Statements for further discussion of uncertain tax positions.

Recent Accounting Pronouncements

Information about recently adopted and proposed accounting pronouncements is included in Note 1 to our Consolidated Financial Statements set forth in Part II, Item 8 of this Annual Report.

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 generally accepted accounting principles in the U.S. (“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 on historical experience, estimated distributor inventory balances, contractual and statutory requirements and other relevant information, and are recorded as a reduction of sales with offsets to trade accounts receivable. The allowance for contractual rebates involves estimating adjustments to revenue based on 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, the related balance of which was $40.0 million of our rebate reserves at January 1, 2023. Our total rebate reserve was $73.5 million at January 1, 2023.

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 October 2, 2022 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 January 1, 2023, we had a valuation allowance of $251.3 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 6 to our Consolidated Financial Statements for more information on income taxes.

Accounting for Business Combinations

Under the acquisition method of accounting, the cost of an acquired business is assigned to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of the estimated fair values at the date of acquisition. We assess fair value, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, using a variety of methods including, but not limited to, an income

approach and a market approach, such as the estimation of future cash flows of the acquired business and current selling prices of similar assets. These valuations require us to make estimates and assumptions, especially with respect to intangible assets.

Fair value of the assets acquired and liabilities assumed, including intangible assets, in-process research and development ("IPR&D"), and contingent payments, are measured based on the assumptions and estimations with regards to variable factors such as the amount and timing of future cash flows for the asset or liability being measured, appropriate risk-adjusted discount rates, nonperformance risk, or other factors that market participants would consider. Upon acquisition, we determine the estimated economic lives of the acquired intangible assets for amortization purposes, which are based on the underlying expected cash flows of such assets. When applicable, adjustments to inventory are based on the fair market value of inventory and are recognized into income based on the period in which the underlying inventory is sold. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that is not individually identified and separately recognized. Actual results may vary from projected results and assumptions used in the fair value assessments.

If the initial accounting for a business combination is incomplete by the end of a reporting period that falls within the measurement period, we report provisional amounts in our financial statements. During the measurement period, we adjust the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. We record these adjustments to the provisional amounts with a corresponding offset to goodwill. Any adjustments identified after the measurement period are recorded in the Consolidated Statements of Income.

Inventories

We periodically review inventory for both potential obsolescence and potential declines in anticipated selling prices. In this review, we make assumptions about the future demand for and market value of the inventory and based on these assumptions estimate the amount of any obsolete, unmarketable, slow moving or overvalued inventory. We write down the value of our inventories by an amount equal to the difference between the cost of the inventory and the net realizable value. If actual market conditions are less favorable than those projected by management at the time of the assessment, however, additional inventory write-downs may be required, which could reduce our earnings.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our business and financial results are affected by fluctuations in world financial markets, including interest rates and currency exchange rates. We manage these risks through normal operating and financing activities and, when deemed appropriate, through the use of derivative financial instruments. We have policies governing our use of derivative instruments, and we do not enter into financial instruments for trading or speculative purposes.

Interest Rate Risk

We are subject to interest rate market risk in connection with our long-term debt. Our principal interest exposure relates to outstanding amounts under our Credit Agreement. Our Credit Agreement provides for variable rate borrowings of up to $2,750.0 million under the Term Loan and $800.0 million under the Revolving Credit Facility. Assuming facilities under the Credit Agreement are fully drawn, each one-eighth percentage point increase or decrease in the applicable interest rates would correspondingly change our interest expense on our outstanding borrowings under the Credit Agreement by approximately $4.3 million per year before considering the impact of derivative instruments. For further discussion of the risks related to our Credit Agreement, see "Risk Factors—Corporate Finance Risks—Our substantial indebtedness could adversely affect our financial condition, limit our ability to raise additional capital to fund our operations and prevent us from fulfilling our obligations under our indebtedness" in Part I, Item 1A, "Risk Factors" of this Annual Report.

We selectively use derivative instruments to reduce market risk associated with changes in interest rates. The use of derivatives is intended for hedging purposes only, and we do not enter into derivative instruments for speculative purposes.

We have entered into an interest rate swap agreement, which fixed a portion of the variable interest due on our variable rate debt. Under the terms of the agreement, we will pay a fixed rate of 1.58% and receive a variable rate of interest based on the USD-SOFR rate from the counterparty, which is reset every month through December 31, 2023. As of January 1, 2023, the notional amount of the interest rate swap was $500.0 million.

In the fourth quarter of 2022, we entered into interest rate swap contracts, commencing on December 30, 2022, with a total notional value of $1.3 billion through December 29, 2023 and $1.8 billion subsequently, to hedge future interest rate exposures on variable rate debt, including the Revolving Credit Facility and Term Loan. During the fourth quarter of 2022, we terminated our non-designated $1.0 billion notional value 3.428% interest rate cap.

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 January 1, 2023 consisted

primarily of government money market funds and other high credit quality debt securities. 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 exchange risk by virtue of our international 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. We derived approximately 25% of our Total revenues for the fiscal year ended January 1, 2023, from operations outside the U.S. For translation of operations in non-U.S. Dollar currencies, the local currency of most entities is the functional currency. Foreign exchange effects from the translation of our balance sheet resulted in a comprehensive loss of $69.8 million for the fiscal year ended January 1, 2023. Foreign exchange effects from the translation of our balance sheet were not material during the fiscal year ended January 2, 2022. Adjustments resulting from the re-measurement of transactions denominated in foreign currencies other than the functional currency of our subsidiaries are expensed as incurred.

In the majority of our jurisdictions, we earn revenue and incur costs in the currency used in such jurisdiction. We incur significant costs in foreign currencies, including Brazilian Real, British Pound, Chinese Yuan/Renminbi, Euro, Indian Rupee, Japanese Yen, Mexican Peso, and the Swiss Franc. As a result, movements in exchange rates cause our revenue and expenses to fluctuate, impacting our profitability and cash flows. Future business operations and opportunities, including the continued expansion of our business outside North America, may further increase the risk that cash flows resulting from these activities may be adversely affected by changes in currency exchange rates.

Like many multi-national companies, we have exposure to the British Pound. We are negatively impacted by a lower British Pound exchange rate from translation impact when compared to the U.S. Dollar, but we also benefit from expenses denominated in British Pound, as well as some cross-border transactions at a lower exchange rate. The magnitude of the impact is dependent on our business volumes in the U.K., forward contract hedge positions, cross currency volume and the exchange rate.

Additionally, in order to fund the purchase price for the assets and capital stock of certain non-U.S. entities, a combination of equity contributions and intercompany loans were utilized to capitalize certain non-U.S. subsidiaries. In many instances, the intercompany loans are denominated in currencies other than the functional currency of the affected subsidiaries. Where intercompany loans are not a component of permanently invested capital of the affected subsidiaries, increases or decreases in the value of the subsidiaries' functional currency against other currencies will affect our results of operations. During the fiscal year ended January 1, 2023, we recorded net foreign currency exchange loss of $6.0 million. Net foreign currency exchange impact was not material for the fiscal year ended January 2, 2022. The foreign currency gains/losses in each period primarily consist of unrealized gains/losses related to intercompany loans denominated in currencies other than the functional currency of the affected subsidiaries. We may enter into derivative instruments to manage our foreign currency exposure on these intercompany loans in the future.

We have entered into foreign currency forward contracts to manage our foreign currency exposures on foreign currency denominated firm commitments and forecasted foreign currency denominated intercompany and third-party transactions. We had forward contracts outstanding with total notional amount of $1,023.3 million as of January 1, 2023, with maturity dates through December 2023. Foreign currency forward contracts that qualified and were designated for hedge accounting are recorded at their fair value as of January 1, 2023 and the unrealized loss of $7.9 million is reported as a component of Other comprehensive income (loss), all of which is expected to be reclassified to earnings in the next 12 months. Actual gains (losses) upon settlement will be recognized in earnings, within the line item impacted, during the estimated time in which the transactions are incurred. Actual gains upon settlement recognized in earnings during the fiscal year ended January 1, 2023 were $3.5 million. Actual losses/gains upon settlement recognized in earnings during the fiscal year ended January 2, 2022 were not material.

See Note 14 to our Consolidated Financial Statements for additional information related to such forward contracts, which information is incorporated herein by reference.

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 QuidelOrtho Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of QuidelOrtho Corporation (the Company) as of January 1, 2023 and January 2, 2022, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended January 1, 2023, and the related notes (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 January 1, 2023 and January 2, 2022, and the results of its operations and its cash flows for each of the three years in the period ended January 1, 2023, 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 January 1, 2023, 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 23, 2023 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Reserve for contractual rebates

Description of the Matter

As described in Note 1 and Note 7 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 January 1, 2023, the Company recognized an allowance on accounts receivable of $40.0 million in rebates which are dependent on estimated rebate percentages that vary based on end-user sales mix.

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 management's evaluation of third-party data inputs utilized in the reserve calculations, as well as the Company's data inputs such as accuracy of contractual pricing and reasonableness of estimated end user sales.

Our audit procedures also included, among others, the evaluation of the Company's retrospective analysis of rebates claimed compared to actual payments issued 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 agreement of contractual rebate amounts to underlying customer contracts.

Valuation of intangible assets acquired in connection with the acquisition of Ortho

Description of the Matter	As described in Note 2 to the consolidated financial statements, on May 27, 2022, Quidel and Ortho consummated the Combinations, with Quidel considered the accounting and legal acquirer for total purchase consideration of approximately $4.3 billion. The transaction was accounted for as a business combination. The Company measured the assets acquired and liabilities assumed at fair value, which resulted in the recognition of approximately $3.2 billion of intangible assets, comprised of customer relationships, developed technology, and trademarks. Auditing the Company's accounting for its acquisition of Ortho was complex due to the significant estimation uncertainty in determining the fair value of the identified intangible assets. A significant emphasis is placed on the appropriateness of key estimates used by management to determine the fair value of the acquired intangible assets due to sensitivity of the resulting fair values to these underlying assumptions. The Company used an income approach to measure the intangible assets. The significant assumptions used to estimate the value of the intangible assets included discount rates and certain assumptions that form the basis of the forecasted results, including revenue growth rates and customer attrition.
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 for determining the fair value of intangible assets acquired. This included controls over management's development of the above-described assumptions used in the valuation models applied. To test the estimated fair value of the intangible assets, we performed audit procedures that included, among others, evaluating the Company's use of the income approach and testing the significant assumptions used in the valuation model, as described above. We evaluated the completeness and accuracy of underlying data used in supporting the assumptions and estimates. We evaluated the reasonableness of projected revenue growth used within the valuations against industry trends and other market information. In addition, we involved valuation specialists to assist in assessing the significant assumptions and methodologies used by the Company.

/s/ Ernst & Young LLP

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

San Diego, California

February 23, 2023

QUIDELORTHO CORPORATION

CONSOLIDATED BALANCE SHEETS

(In millions, except par value)

	January 1, 2023	January 2, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 292.9	$ 802.8
Marketable securities	52.1	25.7
Accounts receivable, net	453.9	378.0
Inventories	524.1	198.8
Prepaid expenses and other current assets	252.1	35.0
Total current assets	1,575.1	1,440.3
Property, plant and equipment, net	1,339.0	349.2
Marketable securities	21.0	37.9
Right-of-use assets	181.0	127.6
Goodwill	2,476.8	337.0
Intangible assets, net	3,123.8	98.7
Deferred tax asset	16.4	20.1
Other assets	122.7	19.6
Total assets	$ 8,855.8	$ 2,430.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 283.3	$ 101.5
Accrued payroll and related expenses	139.2	40.4
Income tax payable	51.6	66.9
Current portion of borrowings	207.5	0.3
Other current liabilities	325.4	114.4
Total current liabilities	1,007.0	323.5
Operating lease liabilities	186.4	128.6
Long-term borrowings	2,430.8	0.4
Deferred tax liability	213.2	—
Other liabilities	83.8	48.5
Total liabilities	3,921.2	501.0
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5.0 shares authorized; none issued or outstanding at January 1, 2023 and January 2, 2022	—	—
Common stock, $0.001 par value per share; 126.2 and 97.5 shares authorized; 66.4 and 41.7 shares issued and outstanding at January 1, 2023 and January 2, 2022, respectively	—	—
Additional paid-in capital	2,804.3	279.8
Accumulated other comprehensive (loss) income	(67.6)	0.4
Retained earnings	2,197.9	1,649.2
Total stockholders' equity	4,934.6	1,929.4
Total liabilities and stockholders' equity	$ 8,855.8	$ 2,430.4

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF INCOME

(In millions, except per share data)

	Fiscal Year Ended		
	2022	2021	2020
Total revenues	$ 3,266.0	$ 1,698.6	$ 1,661.7
Cost of sales, excluding amortization of intangibles	1,330.0	420.3	305.4
Selling, marketing and administrative	621.0	239.6	180.7
Research and development	190.5	95.7	84.3
Amortization of intangible assets	132.5	27.4	27.3
Acquisition and integration costs	136.0	9.6	3.7
Other operating expenses	12.3	—	—
Operating income	843.7	906.0	1,060.3
Interest expense, net	75.7	5.8	8.5
Loss on extinguishment of debt	24.0	—	10.4
Other expense (income), net	8.1	(0.1)	1.1
Income before provision for income taxes	735.9	900.3	1,040.3
Provision for income taxes	187.2	196.1	230.0
Net income	$ 548.7	$ 704.2	$ 810.3
Basic earnings per share	$ 9.66	$ 16.74	$ 19.24
Diluted earnings per share	$ 9.56	$ 16.43	$ 18.60
Weighted-average shares outstanding - basic	56.8	42.1	42.1
Weighted-average shares outstanding - diluted	57.4	42.9	43.6

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In millions)

	Fiscal Year Ended		
	2022	2021	2020
Net income	$ 548.7	$ 704.2	$ 810.3
Other comprehensive income (loss)			
Changes in cumulative translation adjustment, net of tax	(69.8)	(1.6)	2.5
Changes in unrealized losses from investments, net of tax	(0.4)	(0.1)	—
Changes from pension and other post-employment benefits, net of tax	0.7	—	—
Changes in unrealized gains (losses) from cash flow hedges, net of tax:			
Net unrealized gains (losses) on derivative instruments	6.7	0.1	(3.0)
Reclassification of net realized (gains) losses on derivative instruments included in net income	(5.2)	2.4	0.5
Total change in unrealized gains (losses) from cash flow hedges, net of tax	1.5	2.5	(2.5)
Comprehensive income	$ 480.7	$ 705.0	$ 810.3

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In millions)

	Common Stock					
	Shares	Par	Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
Balance at December 29, 2019	41.9	$ —	$ 425.6	$ (0.4)	$ 134.7	$ 559.9
Issuance of common stock under equity compensation plans	0.5	—	10.4	—	—	10.4
Stock-based compensation expense	—	—	19.0	—	—	19.0
Issuance of shares in exchange for Convertible Notes	0.2	—	7.2	—	—	7.2
Tax impact from the conversion of Convertible Notes	—	—	0.1	—	—	0.1
Derivative liabilities - Convertible Notes elected to settle in cash	—	—	(26.2)	—	—	(26.2)
Tax withholdings related to vesting of stock-based awards	—		(4.3)			(4.3)
Repurchases of common stock	(0.3)	—	(43.7)	—	—	(43.7)
Net income	—	—	—	—	810.3	810.3
Balance at January 3, 2021	42.3	$ —	$ 388.1	$ (0.4)	$ 945.0	$ 1,332.7
Issuance of common stock under equity compensation plans	0.6	—	9.6	—	—	9.6
Stock-based compensation expense	—	—	22.7	—	—	22.7
Tax withholdings related to vesting of stock-based awards	(0.2)	—	(37.1)	—	—	(37.1)
Repurchases of common stock	(1.0)	—	(103.5)	—	—	(103.5)
Other comprehensive income, net of tax	—	—	—	0.8	—	0.8
Net income	—	—	—	—	704.2	704.2
Balance at January 2, 2022	41.7	$ —	$ 279.8	$ 0.4	$ 1,649.2	$ 1,929.4
Issuance of common stock under equity compensation plans	0.7	—	30.8	—	—	30.8
Stock-based compensation expense	—	—	45.1	—	—	45.1
Issuance of shares in connection with the Combinations	25.1	—	2,495.4	—	—	2,495.4
Issuance of equity replacement awards in connection with the Combinations	—	—	36.1	—	—	36.1
Tax withholdings related to vesting of stock-based awards	(0.1)	—	(8.6)	—	—	(8.6)
Repurchases of common stock	(1.0)	—	(74.3)	—	—	(74.3)
Other comprehensive loss, net of tax	—	—	—	(68.0)	—	(68.0)
Net income	—	—	—	—	548.7	548.7
Balance at January 1, 2023	66.4	$ —	$ 2,804.3	$ (67.6)	$ 2,197.9	$ 4,934.6

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Fiscal Year Ended		
	2022	2021	2020
OPERATING ACTIVITIES:			
Net income	$ 548.7	$ 704.2	$ 810.3
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	283.6	52.7	48.8
Stock-based compensation expense	48.4	25.4	21.0
Net change in operating lease right-of-use assets and liabilities	18.4	3.0	0.4
Payment of accreted interest on contingent and deferred consideration	(10.4)	(8.2)	—
Loss on extinguishment of debt	24.0	—	10.4
Unwind inventory fair value adjustment	60.6	—	—
Other non-cash, net	(34.8)	31.6	(10.0)
Changes in assets and liabilities:			
Accounts receivable	150.2	118.9	(402.1)
Inventories	(116.9)	(85.0)	(54.9)
Prepaid expenses and other current and non-current assets	(26.2)	(13.3)	(14.3)
Accounts payable	23.5	10.4	52.2
Accrued payroll and related expenses	18.2	5.0	16.0
Income taxes payable	(26.8)	(66.7)	137.7
Other current and non-current liabilities	(75.2)	27.9	14.2
Net cash provided by operating activities	885.3	805.9	629.7
INVESTING ACTIVITIES			
Acquisitions of property, equipment, investments and intangibles	(140.9)	(292.8)	(64.9)
Acquisition of businesses, net of cash and restricted cash acquired	(1,511.4)	—	—
Proceeds from government assistance allocated to fixed assets	18.4	36.9	1.6
Purchases of marketable securities	(63.7)	(67.4)	—
Proceeds from sale of marketable securities	53.4	3.8	—
Net cash used for investing activities	(1,644.2)	(319.5)	(63.3)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	26.4	7.6	9.6
Proceeds from long-term borrowings, net of debt issuance costs	2,734.5	—	—
Payments on long-term borrowings and extinguishment costs	(2,388.3)	(0.3)	(0.5)
Payments of tax withholdings related to vesting of stock-based awards	(8.6)	(37.1)	(4.3)
Repurchases of common stock	(74.3)	(103.5)	(43.7)
Principal payments of acquisition contingent consideration	(4.2)	(4.7)	(6.0)
Principal payments of deferred consideration	(33.5)	(35.1)	(42.0)
Payment on Convertible Senior Note and Derivative Liability	—	—	(43.4)
Net cash provided by (used for) financing activities	252.0	(173.1)	(130.3)
Effect of exchange rates on cash	(2.0)	(0.4)	1.0
Net (decrease) increase in cash, cash equivalents and restricted cash	(508.9)	312.9	437.1
Cash, cash equivalents and restricted cash at beginning of period	802.8	489.9	52.8
Cash, cash equivalents and restricted cash at end of period	$ 293.9	$ 802.8	$ 489.9
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid during the period for interest	$ 95.1	$ —	$ 0.5
Cash paid during the period for income taxes	$ 264.8	$ 235.6	$ 109.9
Purchase of property, equipment and intangibles by incurring current liabilities	$ 40.4	$ 10.5	$ 7.2
Capital expenditures to be reimbursed under a government contract	$ —	$ —	$ 15.9
Transfer of instrument inventories to fixed assets	$ 73.7	$ —	$ —
Reduction of other current liabilities upon issuance of restricted share units	$ 4.6	$ 2.0	$ 0.8
Extinguishment of Convertible Notes through issuance of stock	$ —	$ —	$ 7.2

See accompanying notes.

Note 1. Basis of Presentation and Summary of Significant Accounting Policies

Organization and Business

On May 27, 2022, pursuant to the BCA, Quidel and Ortho consummated the Combinations and each of Quidel and Ortho became a wholly owned subsidiary of QuidelOrtho. As a result of the Combinations, QuidelOrtho became the successor issuer to Quidel. The results of operations of Ortho have been included in the Company's Consolidated Financial Statements from the date of acquisition. See Note 2 for further information regarding the Combinations.

The Company's mission is to develop and manufacture intelligent diagnostic solutions that transform the power of diagnostics into a healthier future for everyone. The Company's expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine helps clinicians and patients make better informed decisions across the globe. The Company's global infrastructure and commercial reach support its customers across more than 130 countries and territories with quality diagnostics, a broad test portfolio and market-leading service. The Company operates globally with manufacturing facilities in the U.S. and U.K. and with sales centers, administrative offices and warehouses located throughout the world.

Basis of Presentation

The accompanying Consolidated Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the U.S. ("GAAP").

Accounting Periods

The Company follows the concept of a fiscal year that ends on the Sunday nearest to the end of the month of December, and fiscal quarters that end on the Sunday nearest to the end of the months of March, June, and September. For fiscal years 2022, 2021 and 2020, the Company's fiscal years ended on January 1, 2023, January 2, 2022 and January 3, 2021, respectively. Fiscal years 2022 and 2021 were 52 weeks and fiscal year 2020 was 53 weeks.

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, liabilities, revenues and expenses and the related 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. The estimates and underlying assumptions can impact all elements of the financial statements, including, but not limited to, accounting for deductions from revenues (e.g. rebates, sales allowances, and discounts), receivable and inventory valuations, fixed asset valuations, useful lives, impairment of goodwill and tangible and intangible assets, the fair value of assets acquired and liabilities assumed in a business combination and related purchase price allocation, long-term employee benefit obligations, income taxes, environmental matters, litigation and allocations of costs. Estimates are based on historical experience, complex judgments, facts and circumstances available at the time and various other assumptions that are believed to be reasonable under the circumstances but are inherently uncertain and unpredictable. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts were reclassified to conform to the current period presentation, including the separate presentation of Amortization of intangible assets and Interest expense, net, the combination of Selling, marketing and administrative expense, and reclassification of Other current liabilities and Other liabilities, which did not change the reported amounts of Total current liabilities or Total liabilities. Cost of sales, excluding amortization of intangibles for fiscal years 2021 and 2020 excludes $7.4 million and $7.4 million, respectively, of intangibles amortization expense, formerly included in Cost of sales, which has been reclassified to Amortization of intangible assets. Selling, marketing and administrative expense for fiscal years 2021 and 2020 excludes $20.0 million and $19.9 million, respectively, of intangibles amortization expense, formerly included in Sales and marketing expense, which has been reclassified to Amortization of intangible assets. The reclassifications did not have an impact on net assets, Operating income, Net income, Basic or Diluted earnings per share, or cash flows.

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. They are carried at cost plus accrued interest, which approximates fair value because of the short-term maturity of these

instruments. Cash equivalents include money market funds and debt securities of high quality institutions. Cash balances may exceed government insured limits in certain jurisdictions.

Marketable Securities

The Company invests excess cash balances in investment-grade corporate debt securities, asset-backed securities and U.S. 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 and Allowance for Credit Losses and Concentration of Credit Risk

The Company sells its products directly to physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies, wellness screening centers, other POC settings, blood banks and donor centers, as well as to individual, non-professional OTC customers, and other distributors in the U.S. and internationally (see Note 4). 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 Company establishes a reserve based on historical losses, the age of receivables, customer mix and credit policies, current economic conditions in customers' country or industry, and expectations associated with reasonable and supportable forecasts, and specific allowances for large or risky accounts. Amounts later determined to be uncollectible are charged or written off against this allowance. The balance of accounts receivable is net of reserves of $89.1 million and $52.4 million at January 1, 2023 and January 2, 2022, respectively, of which the reserve related to contract rebates was $73.5 million and $40.3 million, respectively.

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 using the straight-line method as follows:

Asset type	Useful life
Building and building improvements	7-47 years
Machinery and equipment	3-15 years
Customer leased instruments	3-8 years
Computer software	3-5 years

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.

When assets are surrendered, retired, sold or otherwise disposed of, their gross carrying values and related accumulated depreciation are removed from the accounts and included in determining gain or loss on such disposals. Maintenance and repairs are expensed as incurred; major replacements and improvements that extend the useful life are capitalized.

Goodwill

Goodwill represents the excess of purchase price over the fair values of underlying net assets acquired in an acquisition. The Company assesses goodwill for impairment at the reporting unit level on an annual basis, or whenever events or changes in circumstances occur that indicate that the fair value of a reporting unit is below its carrying amount. Beginning in 2022, the Company changed its annual impairment assessment date from December 31 to the first day of the fourth quarter of the fiscal year.

In connection with the Combinations, the manner in which the chief operating decision maker ("CODM") reviews the Company's performance and allocates resources changed, resulting in six operating segments: North America, EMEA, China, Latin America, Japan and Asia Pacific. North America, EMEA and China are the Company's reportable segments; Latin America, Japan and Asia Pacific are immaterial operating segments that are not considered reportable segments and are included in "Other." The Company concluded each of these six operating segments is considered a reporting unit for the purpose of allocating goodwill and performing the annual goodwill impairment assessment. Prior to the Combinations, the Company operated as a single reportable segment with one reporting unit.

When testing goodwill for impairment, the Company first has an option to assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not (more than 50%) that impairment exists. Such qualitative factors may include the following: macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, and other relevant entity-specific events. In the event the qualitative assessment indicates that an impairment is more likely than not, the Company would be required to perform a quantitative impairment test. Under the quantitative goodwill impairment test, the evaluation of impairment involves comparing the current fair value of each reporting unit to its carrying value, including goodwill. The Company estimates the fair value of its reporting units by using forecasts of discounted future cash flows and peer market multiples. If the fair value of a reporting unit is less than its carrying value, impairment will be recognized in the amount by which the carrying value exceeds the fair value.

For fiscal year 2022, the Company performed a qualitative goodwill impairment assessment as of the beginning of the fiscal fourth quarter to assess for potential impairment. Based on the qualitative impairment assessment performed by the Company, it was concluded that it is not more likely than not that the fair value of the Company's reporting units is less than their carrying amounts, and therefore no further impairment testing was necessary.

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.

Long-lived Assets

The process of evaluating the potential impairment of long-lived assets, such as property, plant and equipment and intangible assets, is subjective and requires judgment. The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of an asset may not be recoverable. If these circumstances exist, recoverability of assets to be held and used is measured by a comparison of the carrying value of an asset group to future undiscounted net cash flows expected to be generated by the asset group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

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. During fiscal year 2020, the remaining aggregate principal amount of the Company's Convertible Notes was settled or matured.

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 on 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 fiscal years 2022 and 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 January 1, 2023 and January 2, 2022, 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 on 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 for fiscal years 2022, 2021 and 2020.

Government Assistance

During fiscal year 2020, the Company entered into a contract with the National Institutes of Health ("NIH"), through its newly launched Rapid Acceleration of Diagnostics - Advanced Technology Platforms initiative, to support the Company's expansion of its manufacturing capacity for its diagnostic assays that test for the SARS-CoV-2 antigen. The contract 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 included key deliverables and milestones that directly supported the upgrade and addition of new manufacturing lines, as well as the outfitting of the new distribution center. The Company also provided instruments and assays to NIH. There were no refund provisions under the contract.

Consideration from the contract was allocated to each deliverable identified within the contract using a relative fair value allocation method and recognized when there was reasonable assurance the Company would meet the milestones and receive the consideration. Consideration allocated to the delivery of instruments and assays was recognized in accordance with the Company's existing revenue recognition policy described above. Consideration that related to capital expenditures was 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 was recorded as reductions to the related expense. As of January 2, 2022, the Company had achieved and collected payments for all milestones under the NIH contract.

In connection with the Combinations, the Company acquired a previously established agreement between Ortho and the Biomedical Advanced Research and Development Authority ("BARDA"), a division of HHS, which provides funding for Ortho to build manufacturing space and production support equipment to increase COVID-19 assay production capacity, as well as to build a manufacturing facility to produce certain analyzers needed to support COVID-19 testing. Amounts received from BARDA under this grant are recorded as a reduction to the carrying value of the related assets. A portion of the grant is

for purposes of reimbursement of certain general and administrative expenses related to the project, which are not capitalized as part of the equipment constructed in connection with the project and are recorded as a reduction to the related expense. The Company received $18.4 million during fiscal year 2022, which was recorded as a reduction to the carrying value of the related assets.

Research and Development Costs

Research and development costs are charged to operations as incurred. Upfront and milestone payments made to third parties in connection with R&D collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties at or subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements to develop and commercialize intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including R&D, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations.

Product Shipment Costs

Product shipment costs are included in Selling, marketing and administrative expense in the accompanying Consolidated Statements of Income. Shipping and handling costs were $104.9 million, $29.3 million and $14.2 million for fiscal years 2022, 2021 and 2020, respectively.

Advertising Costs

Advertising costs are expensed as incurred and included in Selling, marketing and administrative expense in the accompanying Consolidated Statements of Income. Advertising costs were $26.8 million, $13.7 million and $1.1 million for fiscal years 2022, 2021 and 2020, 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.

The Company does not intend to permanently reinvest earnings of foreign subsidiaries at this time. As such, the Company provides for income taxes and foreign withholding taxes, where applicable, on undistributed earnings. Any repatriation of undistributed earnings would be done at little or no tax cost.

Fair Value of Financial Instruments

The Company uses the fair value hierarchy established in 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

Stock-based compensation, comprised of stock options, restricted stock units ("RSUs") and restricted stock awards to employees and directors, is measured at fair value on the grant date. Compensation expense is recognized over the requisite service period, which is generally the vesting period, and includes an estimate of the awards that will be forfeited, and an estimate of the level of performance the Company will achieve for performance-based awards.

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.

Comprehensive Income

Comprehensive income includes unrealized gains and losses that are related to cumulative translation adjustments; unrealized gains and losses on marketable securities; changes in unamortized pension and post-employment actuarial gains and losses; and changes in the fair value of derivatives that are designated and qualify as cash flow hedging instruments excluded from the Consolidated Statements of Income.

Business Combinations

The cost of an acquired business is assigned to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of the estimated fair values at the date of acquisition. The Company assesses fair value, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, using a variety of methods including, but not limited to, an income approach and a market approach, such as the estimation of future cash flows of the acquired business and current selling prices of similar assets. Fair value of the assets acquired and liabilities assumed, including intangible assets, IPR&D, and contingent payments, are measured based on the assumptions and estimations with regards to variable factors such as the amount and timing of future cash flows for the asset or liability being measured, appropriate risk-adjusted discount rates, nonperformance risk, or other factors that market participants would consider. Upon acquisition, the Company determines the estimated economic lives of the acquired intangible assets for amortization purposes, which are based on the underlying expected cash flows of such assets. When applicable, adjustments to inventory are based on the fair market value of inventory and are recognized into income based on the period in which the underlying inventory is sold. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that is not individually identified and separately recognized. Actual results may vary from projected results and assumptions used in the fair value assessments.

Defined Benefit Plans and Other Post-Employment Benefits

In connection with the Combinations, the Company assumed Ortho's defined benefit plans in certain countries and a retiree healthcare reimbursement plan for certain U.S. employees. Defined benefit plans specify an amount of pension benefit that an employee will receive on retirement, usually dependent on factors such as age, years of service and compensation. The net obligation with respect to defined benefit plans is calculated separately for each plan by estimating the amount of the future benefits that employees have earned in return for their service in the current and prior periods. These benefits are then discounted to determine the present value of the obligations and are then adjusted for the impact of any unamortized prior service costs. The net obligation is then determined with reference to the fair value of the plan assets (if any). The discount rate used is the yield on bonds that are denominated in the currency in which the benefits will be paid and that have maturity dates approximating the terms of the obligations. The calculations are performed by qualified actuaries using the projected unit credit method.

Recent Accounting Pronouncements

In October 2021, the Financial Accounting Standards Board issued guidance which was codified in Accounting Standards Update 2021-08, Business Combinations (Topic 805) *Accounting for Contract Assets and Contract Liabilities from Contracts*

with Customers. Under the new guidance, an acquirer is required to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, *Revenue from Contracts with Customers*. For public business entities, this guidance is effective for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company early adopted the guidance during the first quarter of 2022 with no material impact to the Consolidated Financial Statements.

Note 2. Business Combination

On May 27, 2022, pursuant to the BCA, Quidel and Ortho consummated the Combinations and each of Quidel and Ortho became a wholly owned subsidiary of QuidelOrtho. As a result of the Combinations, QuidelOrtho became the successor issuer to Quidel. The Combinations have been accounted for as a business combination using the acquisition method of accounting in conformity with ASC Topic 805, *Business Combinations*, with Quidel considered the accounting and the legal acquirer. The Combinations enhance the Company's revenue profile and expand the Company's geographic footprint and product diversity.

The Combinations were completed for a total consideration of approximately $4.3 billion, which included the fair value of equity issued based on the May 26, 2022 closing price of $99.60 per share of Quidel common stock. Former Ortho shareholders received $7.14 in cash and 0.1055 shares of QuidelOrtho common stock for each Ortho ordinary share. The total purchase consideration was calculated as follows (in millions, except value per share data and Ortho Exchange Ratio):

Total Ortho shares subject to exchange		237.487
Ortho Exchange Ratio		0.1055
QuidelOrtho shares issued		25.055
Value per Quidel share as of May 26, 2022	$	99.60
Fair value of stock consideration	$	2,495.5
Fair value of replacement equity awards (1)		47.9
Cash consideration (2)		1,747.7
Total purchase consideration	$	4,291.1

(1) Represents the fair value of replacement stock options (which include options with time-based, performance-based, and both performance- and market-based vesting conditions), RSUs and restricted stock outstanding as of May 27, 2022 that are attributable to service prior to the Combinations. The terms of the replacement awards are substantially similar to the former Ortho equity awards for which they were exchanged. The portion of the fair value of the replacement equity awards attributable to service after the Combinations is $46.6 million and will be recognized as compensation expense based on the vesting terms of the replacement equity awards.

(2) Represents cash consideration of $7.14 per share paid to Ortho shareholders and holders of vested Ortho stock options on the closing date of the Combinations for 237.5 million outstanding Ortho shares and 7.3 million vested Ortho stock options.

The Company funded the cash portion of the purchase price with cash on its balance sheet and a portion of the Term Loan (as defined in Note 8) proceeds from the Financing (as defined in Note 8). See Note 8 for further information regarding the Company's debt.

The components of the preliminary purchase price allocation on the closing date of the Combinations are as follows:

(In millions)	Amounts Recognized as of Acquisition Date (as previously reported)	Measurement Period Adjustments	Amounts Recognized as of Acquisition Date (as adjusted)
Cash and cash equivalents	$ 234.5	$ —	$ 234.5
Accounts receivable	240.6	—	240.6
Inventories	386.8	(2.4)	384.4
Property, plant and equipment	767.5	181.4	948.9
Goodwill	2,291.3	(112.9)	2,178.4
Intangible assets	3,133.0	35.0	3,168.0
Prepaid expenses and other assets	287.9	(16.2)	271.7
Total assets	7,341.6	84.9	7,426.5
Accounts payable	(135.0)	—	(135.0)
Accrued payroll and related expenses	(80.7)	(0.4)	(81.1)
Long-term borrowings, including current portion [(1)]	(2,268.4)	—	(2,268.4)
Deferred tax liability	(215.4)	(63.0)	(278.4)
Other current and non-current liabilities	(351.0)	(21.5)	(372.5)
Total liabilities	(3,050.5)	(84.9)	(3,135.4)
Total purchase consideration	$ 4,291.1	$ —	$ 4,291.1

(1) Immediately following the closing of the Combinations, the Company repaid long-term borrowings assumed, which consisted of $1,608.4 million aggregate principal amount related to Ortho's Dollar Term Loan and Euro Term Loan Facilities, $240.0 million aggregate principal amount of 7.375% Senior Notes due 2025 and $405.0 million aggregate principal amount of 7.250% Senior Notes due 2028. The 7.375% and 7.250% Senior Notes were fully discharged following the Combinations. The Company recorded a $23.5 million loss on extinguishment in connection with the Combinations, representing the difference between the reacquisition value, inclusive of $35.9 million of redemption premium, and the net carrying value of the extinguished debt.

The fair value estimates for the assets acquired and liabilities assumed were based on preliminary calculations, and the Company's estimates and assumptions are subject to change for income tax matters. The Company expects to finalize the valuation as soon as practicable, but no later than one year after the closing date of the Combinations. The measurement period adjustments in the six months ended January 1, 2023 primarily resulted from completing valuations of real estate, personal property and intangible assets and revising the valuation of income tax liabilities. The related impact to net earnings that would have been recognized in previous periods if the adjustments were recognized as of the acquisition date is immaterial to the Consolidated Financial Statements.

Inventories acquired included raw materials, work in progress and finished goods. Inventories were recorded at their estimated fair values. Inventories were valued at the estimated selling price less the estimated costs to be incurred to complete and sell the inventories, the associated margins on these activities and holding costs. A step-up in the value of inventory of $61.7 million was recorded in connection with the Combinations. The step-up value was recorded in Cost of sales, excluding amortization of intangibles in the Consolidated Statements of Income as the inventory was sold to customers, and was fully recognized by the end of fiscal year 2022. In fiscal year 2022, $60.6 million of the fair value step-up of inventory was recognized in the Consolidated Statements of Income.

Goodwill represents the excess of the total purchase consideration over the estimated fair value of the net assets acquired, and is primarily attributable to synergies which are expected to expand the Company's revenue profile and product diversity, as well as Ortho's assembled workforce. Goodwill is not deductible for tax purposes. The preliminary assignment of goodwill by reportable segment as of the closing date of the Combinations is as follows (in millions):

North America	$ 1,211.5
EMEA	370.0
China	121.6
Other	475.3
	$ 2,178.4

The following table sets forth the amounts assigned to the identifiable intangible assets acquired (in millions, except years):

Intangible Asset	Amortization Period	Fair Value of Assets Acquired
Customer relationships	20 years	$ 1,907.0
Developed technology	15 years	888.0
Trademarks	15 years	373.0
		$ 3,168.0

The fair value of customer relationships was estimated using the Multi-Period Excess Earnings Method, which is a form of the income approach. Significant assumptions include: (i) the estimated annual net cash flows, which are a function of expected earnings attributable to the asset, contributory asset charges and the applicable tax rate, and (ii) the discount rate.

The fair value of developed technology and trademarks was estimated using the Relief from Royalty Method, which is another form of the income approach. Significant assumptions include: (i) the estimated annual net cash flows, which are a function of expected earnings attributable to the asset, the probability of use of the asset, the royalty rate and the applicable tax rate, and (ii) the discount rate.

Intangible assets are amortized on a straight-line basis over the amortization periods noted above, which reflects the estimated useful life of the underlying assets.

For fiscal year 2022, the Company incurred $46.9 million of transaction costs related to the Combinations, which primarily consisted of financial advisory, legal, accounting and valuation-related expenses. These expenses were recorded in Acquisition and integration costs in the Consolidated Statements of Income.

The following supplemental pro forma financial information shows the combined results of operations of the Company as if the Combinations had occurred on January 4, 2021, the beginning of the periods presented:

	Fiscal Year Ended	
(In millions) (unaudited)	2022	2021
Pro forma total revenues	$ 4,051.2	$ 3,741.4
Pro forma net income	589.3	613.2

This supplemental pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved had the Combinations been completed at the beginning of fiscal year 2021. In addition, the supplemental pro forma financial information is not a projection of the Company's future results of operations, nor does it reflect the expected realization of any synergies or cost savings associated with the Combinations. The supplemental pro forma financial information includes adjustments for:

- incremental intangible assets amortization expense to be incurred of $19.6 million and $45.5 million for fiscal years 2022 and 2021, respectively, based on the preliminary fair values of the identifiable intangible assets acquired;
- incremental cost of sales related to the fair value step-up of inventory which is reflected by an adjustment to decrease expense by $60.6 million for fiscal year 2022 and an adjustment to increase expense by $61.7 million for fiscal year 2021;
- decreases in interest expense of $11.2 million and $34.9 million for fiscal years 2022 and 2021, respectively, associated with the issuance of debt to finance the Combinations and to repay Ortho's then-outstanding indebtedness, including the net impact of the removal of the amortization of the discount on Ortho's indebtedness and the change in amortization of deferred financing fees;
- the removal of $50.3 million of loss on extinguishment of debt from Ortho's financial results for fiscal year 2022 and the reclassification of $24.0 million of loss on extinguishment of debt incurred during fiscal year 2022 to fiscal year 2021;
- the reclassification of $12.8 million of expense related to the accelerated vesting of certain stock awards of Ortho's former chief executive officer from fiscal year 2022 to fiscal year 2021; and
- tax impacts related to the above adjustments.

From the closing date of the Combinations through January 1, 2023, the acquired results of operations of Ortho contributed total revenues of $1,165.2 million and net loss of $126.2 million to the Company's consolidated results, which included amortization of acquired intangible assets of $104.7 million and recognition in Cost of sales, excluding amortization of intangibles of the fair value step-up of inventory of $60.6 million.

Note 3. Computation of Earnings Per Share

Basic earnings per share ("EPS") is computed by dividing net income by the weighted-average number of shares of common stock outstanding. Diluted EPS is computed based on the sum of the weighted-average number of shares of common stock and potentially dilutive shares of common stock outstanding during the period. Potentially dilutive shares of common stock consist of shares issuable from stock options, unvested RSUs and restricted stock. Potentially dilutive shares of common stock 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:

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Numerator:			
Net income used for basic earnings per share	$ 548.7	$ 704.2	$ 810.3
Interest expense on Convertible Notes, net of tax	—	—	0.4
Net income used for diluted earnings per share, if-converted method	$ 548.7	$ 704.2	$ 810.7
Denominator:			
Basic weighted-average shares of common stock outstanding	56.8	42.1	42.1
Dilutive potential shares issuable from Convertible Notes	—	—	0.3
Dilutive potential shares issuable from stock options and unvested RSUs	0.6	0.8	1.2
Diluted weighted-average shares of common stock outstanding	57.4	42.9	43.6
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	1.5	0.2	—

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

Note 4. Revenue

Contract Balances

Timing of revenue recognition may differ from timing of invoicing to customers. The Company records an asset when revenue is recognized prior to invoicing a customer (a "contract asset"). Contract assets are included within Prepaid expenses and other current assets or Other assets in the Company's Consolidated Balance Sheets and are transferred to accounts receivable when the right to payment becomes unconditional. The balance of contract assets recorded in the Company's Consolidated Balance Sheets as of January 1, 2023 was $49.6 million and was included in Prepaid expenses and other current assets.

The contract asset balance as of January 1, 2023 consisted of the following components, all of which related to agreements acquired by the Company in connection with the Combinations; therefore, no balance existed at January 2, 2022:

- a customer supply agreement under which the difference between the timing of invoicing and revenue recognition resulted in a contract asset of $6.8 million;
- contractual arrangements with certain customers under which the Company invoices the customers based on reportable results generated by its reagents; however, control of the goods transfers to the customers upon shipment or delivery of the products, as determined under the terms of the contract. Using the expected value method, the Company estimates the number of reagents that will generate a reportable result. The Company records the revenue upon shipment and an associated contract asset, and relieves the contract asset upon completion of the invoicing. The balance of the contract asset related to these arrangements was $38.5 million as of January 1, 2023 and was recorded in Prepaid expenses and other current assets; and

- one of the Company's contract manufacturing agreements that recognizes revenue as the products are manufactured. The balance of the contract asset related to this arrangement was $4.3 million as of January 1, 2023.

The Company reviews contract assets for expected credit losses resulting from the collectability of customer accounts. Expected losses are established based on historical losses, customer mix and credit policies, current economic conditions in customers' country or industry, and expectations associated with reasonable and supportable forecasts. No credit losses related to contract assets were recognized during fiscal year 2022.

The Company recognizes a contract liability when a customer pays an invoice prior to the Company transferring control of the goods or services ("contract liabilities"). The Company's contract liabilities consist of deferred revenue primarily related to customer service contracts. The Company classifies deferred revenue as current or non-current based on the timing of the transfer of control or performance of the service. The balance of the Company's current deferred revenue was $76.4 million as of January 1, 2023, and $1.9 million as of January 2, 2022. The Company has one arrangement with a customer where the revenue is expected to be recognized beyond one year. The balance of the deferred revenue included in long-term liabilities was $9.4 million as of January 1, 2023 and was included in Other liabilities in the Consolidated Balance Sheets. There was no deferred revenue included in long-term liabilities as of January 2, 2022.

Joint Business with Grifols

In connection with the Combinations, the Company acquired the Joint Business between Ortho and Grifols, under which Ortho and Grifols agreed to pursue a collaboration relating to Ortho's Hepatitis and HIV diagnostics business. The governance of the Joint Business is shared through a supervisory board made up of equal representation by Ortho and Grifols, which is responsible for all significant decisions relating to the Joint Business that are not exclusively assigned to either Ortho or Grifols, as defined in the Grifols Agreement. The Company's portion of the pre-tax net profit shared under the Joint Business was $18.6 million during fiscal year 2022. This included the Company's portion of the pre-tax net profit of $11.1 million during fiscal year 2022 on sales transactions with third parties where the Company is the principal. The Company recognized revenues, cost of sales, excluding amortization of intangibles, and operating expenses, on a gross basis on these sales transactions in their respective lines in the Consolidated Statements of Income. The Company's portion of the pre-tax net profit also included revenue of $7.5 million from collaboration and royalty agreements during fiscal year 2022, which is presented on a net basis within Total revenues.

Disaggregation of Revenue

Following the Combinations, the Company reorganized its former product categories into four business units. Revenues from the Company's former Specialized Diagnostic Solutions product category have been included in a new Labs business unit. The Company's former Rapid Immunoassay and Cardiometabolic Immunoassay product categories now represent its Point of Care business unit. The Molecular Diagnostics business unit represents the former Molecular Diagnostic Solutions product category. In addition, the Company added a Transfusion Medicine business unit.

The following table summarizes Total revenues by business unit:

	Fiscal Year Ended		
(In millions)	2022	2021	2020
Labs	$ 820.2	$ 44.8	$ 50.9
Transfusion Medicine	393.8	—	—
Point of Care	1,955.3	1,453.3	1,387.8
Molecular Diagnostics	96.7	200.5	223.0
Total revenues	$ 3,266.0	$ 1,698.6	$ 1,661.7

Concentration of Revenue and Credit Risk

The Company had sales to individual customers in excess of 10% of Total revenues as follows:

	Fiscal Year Ended		
	2022	2021	2020
Customer:			
A	20 %	1 %	— %
B	11 %	24 %	29 %
C	8 %	9 %	16 %
D	5 %	9 %	13 %
E	3 %	7 %	10 %
	47 %	50 %	68 %

As of January 1, 2023 and January 2, 2022, customers with balances due in excess of 10% of Accounts receivable, net totaled $161.9 million and $267.3 million, respectively. For fiscal years 2022, 2021 and 2020, sales of COVID-19 products accounted for 44%, 75% and 70% of Total revenues, respectively. For fiscal years 2022, 2021 and 2020, sales of influenza products accounted for 11%, 4% and 8% of Total revenues, respectively.

Note 5. Segment and Geographic Information

In connection with the Combinations, the manner in which the CODM reviews the Company's performance and allocates resources changed, resulting in three geographically-based reportable segments: North America; EMEA; and China. Although all three segments are engaged in the marketing, distribution and sale of diagnostic instruments and assays for hospitals, retailers, distributors, laboratories and/or blood and plasma centers worldwide, each region is managed separately to better align with the market dynamics of the specific geographic region. Latin America, Japan and Asia Pacific are immaterial operating segments that are not considered reportable segments and are included in "Other." Previously, the Company operated as a single reportable segment. Prior periods have been revised to align with the current period presentation.

Total revenues by reportable segment are as follows:

	Fiscal Year Ended		
(In millions)	2022	2021	2020
North America	$ 2,536.5	$ 1,500.2	$ 1,460.7
EMEA	206.8	69.6	92.9
China	220.0	58.0	62.4
Other	302.7	70.8	45.7
Total revenues	$ 3,266.0	$ 1,698.6	$ 1,661.7

Beginning in the second quarter of 2022, in connection with the Combinations, the basis by which the Company measures segment profit or loss changed to Adjusted EBITDA in order to manage the Company's business to better align with the market dynamics of the specific geographic regions in which the Company operates. In the fourth quarter of 2022, the Company revised the internal allocation of certain global costs primarily between the North America segment and Corporate to better align costs that impact the Company as a whole. Prior periods have been revised to align with the current period presentation.

The following table sets forth Adjusted EBITDA by segment and the reconciliations to Income before provision for income taxes for fiscal years 2022, 2021 and 2020:

	Fiscal Year Ended		
(In millions)	2022	2021	2020
North America	$ 1,614.6	$ 1,028.5	$ 1,205.2
EMEA	31.7	28.1	55.5
China	104.1	24.1	30.5
Other	92.7	43.0	28.0
Total segment Adjusted EBITDA	1,843.1	1,123.7	1,319.2
Corporate [1]	(512.1)	(152.9)	(203.9)
Depreciation and amortization	(283.6)	(52.7)	(48.8)
Acquisition and integration costs	(136.0)	(9.6)	(3.7)
Interest expense, net	(75.7)	(5.8)	(8.5)
Unwind inventory fair value adjustment	(60.6)	—	—
Loss on extinguishment of debt	(24.0)	—	(10.4)
(Loss) gain on investments	(5.8)	1.5	—
Amortization of deferred cloud computing implementation costs	(5.4)	(3.7)	(1.1)
Employee compensation charges and other costs	(3.7)	—	—
Impairment of long-lived assets	(2.8)	—	—
EU medical device regulation transition costs [2]	(1.5)	—	—
Tax indemnification expense	(0.3)	—	—
Change in fair value of acquisition contingencies	(0.1)	(0.2)	(1.4)
Derivative mark-to-market gain (loss)	4.4	—	(1.1)
Income before provision for income taxes	$ 735.9	$ 900.3	$ 1,040.3

(1) Primarily consists of costs related to executive and staff functions, including certain finance, human resources, manufacturing and IT functions, which benefit the Company as a whole. These costs are primarily related to the general management of these functions on a corporate level and the design and development of programs, policies and procedures that are then implemented in the individual segments, with each segment bearing its own cost of implementation. The Company's corporate function also includes debt and stock-based compensation associated with all employee stock-based awards.

(2) Represents incremental consulting costs and R&D manufacturing site costs to align compliance of Ortho's existing, on-market products that were previously registered under the European In Vitro Diagnostics Directive regulatory framework with the requirements under the EU's In Vitro Diagnostic Regulation, which generally apply from May 2022 onwards.

The CODM does not review capital expenditures, total depreciation and amortization or assets by segment, and therefore this information has been excluded as it does not comprise part of management's key performance metrics.

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

	Long-lived Assets as of		Total Revenues for Fiscal Year		
(In millions)	January 1, 2023	January 2, 2022	2022	2021	2020
Domestic	$ 983.0	$ 347.1	$ 2,451.7	$ 1,415.5	$ 1,452.4
Foreign	356.0	2.1	814.3	283.1	209.3
Total	$ 1,339.0	$ 349.2	$ 3,266.0	$ 1,698.6	$ 1,661.7

Note 6. Income Taxes

Significant components of the provision for income taxes were as follows:

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Current:			
Federal	$ 162.2	$ 148.8	$ 198.5
State	48.8	42.4	34.6
Foreign	17.6	2.3	1.1
Total current provision	228.6	193.5	234.2
Deferred:			
Federal	(31.9)	7.2	(2.9)
State	(9.3)	(2.6)	(1.0)
Foreign	(0.2)	(2.0)	(0.3)
Total deferred provision (benefit)	(41.4)	2.6	(4.2)
Provision for income taxes	$ 187.2	$ 196.1	$ 230.0

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

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
United States	$ 672.1	$ 891.2	$ 1,035.7
Foreign	63.8	9.1	4.6
Income before income taxes	$ 735.9	$ 900.3	$ 1,040.3

Significant components of the Company's deferred tax assets and deferred tax liabilities as of January 1, 2023 and January 2, 2022 are shown below:

(In millions)	**January 1, 2023**	**January 2, 2022**
Deferred tax assets:		
Lease liability	$ 51.4	$ 32.7
Intangible assets	—	2.2
Allowance for returns and discounts	45.9	28.3
Inventory reserve	34.1	6.4
Stock-based compensation	14.6	9.2
Tax loss and credit carryforwards	565.3	10.8
Research & development expenses	50.7	—
Employee related obligations	19.9	5.5
Other, net	16.1	0.8
Total deferred tax assets	798.0	95.9
Valuation allowance for deferred tax assets	(251.3)	(2.3)
Total deferred tax assets, net of valuation allowance	546.7	93.6
Deferred tax liabilities:		
Right-of-use assets	(43.8)	(30.1)
Intangible assets	(590.2)	(0.9)
Property, plant and equipment	(109.5)	(42.5)
Total deferred tax liabilities	(743.5)	(73.5)
Net deferred tax assets (liabilities)	$ (196.8)	$ 20.1

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 fiscal years ended January 1, 2023, January 2, 2022 and January 3, 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.

The valuation allowance of $251.3 million as of January 1, 2023 represents the portion of the deferred tax asset that management could not conclude was more likely than not to be realized. The Company's valuation allowance relates primarily to the realization of recorded tax benefits on tax loss carryforwards from operations in Luxembourg and certain U.S. state jurisdictions. 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 January 1, 2023, the Company had U.S. federal net operating loss ("NOL") carryforwards of $879.8 million, of which $473.0 million are subject to expiration through 2037 and $406.8 million are not subject to expiration. In addition, the Company has state NOLs of approximately $530.1 million, which will expire in years 2023 through 2042. As of January 1, 2023, the Company had U.S. federal research credit carryforwards of $14.2 million and federal foreign tax credits of $3.4 million, which will begin to expire in 2034 and 2028, respectively. In addition, the Company had state research credits of $5.9 million, of which none expire, and state business credit carryforwards of $25.6 million, which will begin to expire in 2029. As of January 1, 2023, the Company had $543.8 million of NOL carryforwards in certain non-U.S. jurisdictions, net of uncertain tax positions. Of these, $339.1 million have no expiration and the remaining $204.7 million will expire in years through 2042.

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 a result of an ownership change that occurred in the second quarter of fiscal year 2022, the Company may be limited in its ability to utilize its NOL carryforwards and certain other attributes, starting the ownership change date.

The reconciliation of income tax computed at the federal statutory rate to the provision for income taxes from continuing operations was as follows:

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Tax expense at statutory tax rate	$ 154.5	$ 189.1	$ 218.5
State tax expense, net of federal tax	29.3	30.1	30.3
Foreign income taxed at rates other than the applicable U.S. rate	(27.5)	—	—
Permanent differences	12.0	1.8	3.8
Federal and state research credits—current year	(7.3)	(7.7)	(5.0)
Stock-based compensation	1.5	(9.2)	(13.9)
Change in valuation allowance	26.2	(0.1)	(0.1)
Foreign Derived Intangible Income Deduction (FDII)	(10.2)	(8.4)	(8.6)
Other	8.7	0.5	5.0
Provision for income taxes	$ 187.2	$ 196.1	$ 230.0

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:

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Beginning balance	$ 17.7	$ 22.6	$ 17.2
Increases due to current year acquisitions	27.8	—	—
Increases (decreases) related to prior year tax positions	(0.6)	0.5	(2.3)
Increases related to current year tax positions	1.8	0.9	7.7
Decreases from voluntary disclosure agreements	—	(6.3)	—
Decreases due to settlements	(6.7)	—	—
Ending balance	$ 40.0	$ 17.7	$ 22.6

As of January 1, 2023, January 2, 2022 and January 3, 2021, the Company had unrecognized tax benefits of $40.0 million, $17.7 million, and $22.6 million, respectively, of which $28.3 million, $11.3 million and $15.0 million, respectively, would reduce the Company's annual effective tax rate, if recognized. The Company estimates that within the next 12 months, its uncertain tax positions, excluding interest, will decrease by $2.4 million. The uncertain tax positions relate to an on-going multi-state tax commission audit that is expected to be settled within the next 12 months.

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 $8.3 million as of January 1, 2023 and $1.2 million as of January 2, 2022. Interest expense, net of accrued interest (reversed) for fiscal years 2022, 2021 and 2020 was approximately $0.3 million, $0.7 million and $0.1 million, respectively.

The Company is subject to periodic audits by domestic and foreign tax authorities. Due to the carryforward of unutilized credits, the Company's federal tax years from 2012 and onwards are subject to examination by the U.S. authorities. The Company's state and foreign tax years for 2001 and onwards are subject to examination by applicable 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.

Ortho is currently under audit in certain jurisdictions for tax years under the responsibility of Johnson & Johnson. Pursuant to the stock and asset purchase agreement entered into by Ortho and Johnson & Johnson in January 2014, Johnson & Johnson retained all income tax liabilities accrued as of the date of acquisition, including reserves for unrecognized tax benefits. Accordingly, all tax liabilities related to these tax years will be indemnified by Johnson & Johnson. As of January 1, 2023, the indemnification receivable from Johnson & Johnson totaled $16.8 million and is included as a component of Prepaid expenses and other current assets and Other assets on the Consolidated Balance Sheet.

The following table summarizes the changes to the valuation allowance for balances for fiscal years 2022, 2021 and 2020:

	Beginning Balance	Additions Due to Current Year Acquisitions	Additions (Deductions) Charged to Provision for (Benefit From) Income Taxes	Currency Translation/Other	Ending Balance
Deferred tax valuation allowance					
Fiscal year ended January 1, 2023	$ 2.3	223.5	26.2	(0.7)	$ 251.3
Fiscal year ended January 2, 2022	$ 2.3	—	—	—	$ 2.3
Fiscal year ended January 3, 2021	$ 2.4	—	(0.1)	—	$ 2.3

Note 7. Balance Sheet Account Details

Cash, Cash Equivalents and Restricted Cash

(In millions)	January 1, 2023	January 2, 2022
Cash and cash equivalents	$ 292.9	$ 802.8
Restricted cash included in Other assets	1.0	—
Cash, cash equivalents and restricted cash	$ 293.9	$ 802.8

Marketable Securities

The following table is a summary of marketable securities:

(In millions)	January 1, 2023 Amortized Cost	Gross Unrealized Losses	Fair Value	January 2, 2022 Amortized Cost	Gross Unrealized Losses	Fair Value
Corporate bonds	40.5	$ (0.5)	$ 40.0	$ 22.3	$ —	$ 22.3
Corporate asset-backed securities	6.7	—	6.7	3.4	—	3.4
U.S. government securities	2.0	—	2.0	—	—	—
Agency bonds	1.0	—	1.0	—	—	—
Sovereign government bonds	1.9	—	1.9	—	—	—
Foreign and other	0.5	—	0.5	—	—	—
Total marketable securities, current	52.6	(0.5)	52.1	25.7	—	25.7
Corporate bonds, non-current	13.3	(0.1)	13.2	26.8	(0.1)	26.7
Corporate asset-backed securities, non-current	7.9	(0.1)	7.8	11.2	—	11.2
Total marketable securities	$ 73.8	$ (0.7)	$ 73.1	$ 63.7	$ (0.1)	$ 63.6

Accounts Receivable, Net

Accounts receivables primarily consist of trade accounts receivables with maturities of one year or less and are presented net of reserves:

(In millions)	January 1, 2023	January 2, 2022
Accounts receivable	$ 543.0	$ 430.4
Allowance for contract rebates and discounts	(77.1)	(50.7)
Allowance for doubtful accounts	(12.0)	(1.7)
Total accounts receivable, net	$ 453.9	$ 378.0

The allowance for contractual rebates involves estimating adjustments to revenue based on 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, the related balance of which was $40.0 million and $40.3 million at January 1, 2023 and January 2, 2022, respectively, and was included in the allowance for contract rebates and discounts.

The following table summarizes changes to the accounts receivable allowance balances for fiscal years 2022, 2021 and 2020:

(In millions)	Balance at Beginning of Period	Additions Charged to Expense or as Reductions to Revenue (1)	Deductions (2)	Balance at end of period
Fiscal year ended January 1, 2023	$ 52.4	$ 407.6	$ (370.9)	$ 89.1
Fiscal year ended January 2, 2022	$ 103.4	$ 456.2	$ (507.2)	$ 52.4
Fiscal year ended January 3, 2021	$ 15.9	$ 277.0	$ (189.5)	$ 103.4

(1) Includes opening balance of $31.4 million related to the Combinations during fiscal year 2022. Primarily represents charges for contract rebate allowances recorded as reductions to revenue. Additions to allowance for doubtful accounts are recorded to selling, marketing and administrative expense.

(2) The deductions represent actual charges against the accrual described above.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. Inventories consisted of the following:

(In millions)	January 1, 2023	January 2, 2022
Raw materials	$ 185.2	$ 103.2
Work-in-process (materials, labor and overhead)	82.7	36.1
Finished goods (materials, labor and overhead)	295.1	59.5
Total inventories	$ 563.0	$ 198.8
Inventories	$ 524.1	$ 198.8
Other assets [1]	38.9	—
Total inventories	$ 563.0	$ 198.8

(1) Other assets includes inventory expected to remain on hand beyond one year.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(In millions)	January 1, 2023	January 2, 2022
Prepaid expenses	$ 96.7	$ 14.6
Contract assets	49.6	—
Other receivables	44.3	15.8
Income taxes and other tax receivables	38.6	—
Derivatives	22.0	0.1
Other	0.9	4.5
Total prepaid expenses and other current assets	$ 252.1	$ 35.0

Property, Plant and Equipment, Net

The following is a summary of property, plant and equipment:

(In millions)	January 1, 2023	January 2, 2022
Equipment, furniture and fixtures	$ 515.1	$ 159.0
Building and improvements	364.7	146.8
Customer leased instruments	434.5	68.1
Land	34.5	10.2
Construction in progress	268.4	105.2
Total property, plant and equipment, gross	1,617.2	489.3
Less: accumulated depreciation and amortization	(278.2)	(140.1)
Total property, plant and equipment, net	$ 1,339.0	$ 349.2

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 certain 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 $151.1 million, $24.3 million and $20.8 million for fiscal years 2022, 2021 and 2020, respectively.

Goodwill and Intangible Assets

Changes in goodwill were as follows:

(In millions)	North America	EMEA	China	Other	Total
Balance at January 2, 2022					$ 337.0
Impact of reportable segment revisions	$ 336.9	$ 0.1	$ —	$ —	337.0
Goodwill acquired	1,211.5	370.0	121.6	475.3	2,178.4
Foreign currency translation	(0.7)	(11.5)	(3.5)	(22.9)	(38.6)
Balance at January 1, 2023	$ 1,547.7	$ 358.6	$ 118.1	$ 452.4	$ 2,476.8

Intangible assets consisted of the following:

		January 1, 2023			January 2, 2022		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	14.3	$ 997.6	$ (120.0)	$ 877.6	$ 112.7	$ (78.2)	$ 34.5
Customer relationships	19.2	2,023.5	(148.9)	1,874.6	122.7	(77.3)	45.4
License agreements	6.4	3.8	(3.7)	0.1	6.6	(5.7)	0.9
Patent and trademark costs	14.7	400.5	(32.8)	367.7	28.7	(15.7)	13.0
Software development costs	4.7	11.5	(7.7)	3.8	11.7	(6.8)	4.9
Total intangible assets		$ 3,436.9	$ (313.1)	$ 3,123.8	$ 282.4	$ (183.7)	$ 98.7

Amortization expense related to the capitalized software costs was $0.9 million, $1.0 million and $0.9 million for fiscal years 2022, 2021 and 2020, respectively. Amortization expense (including capitalized software costs) was $132.5 million, $27.4 million and $27.3 million for fiscal years 2022, 2021 and 2020, respectively.

The expected future annual amortization expense of the Company's finite-lived intangible assets held as of January 1, 2023 is as follows:

(In millions)	
2023	$ 205.4
2024	201.7
2025	188.2
2026	187.1
2027	184.7

Other Current Liabilities

Other current liabilities consist of the following:

(In millions)	January 1, 2023	January 2, 2022
Accrued commissions and rebates	$ 55.1	$ 15.9
Deferred consideration	39.3	41.9
Deferred revenue	76.4	1.9
Operating lease liabilities	24.4	10.0
Accrued other taxes payable	9.3	10.2
Derivatives	19.7	0.3
Contingent consideration	0.1	6.0
Payables under transition services agreements	—	10.9
Other	101.1	17.3
Total other current liabilities	$ 325.4	$ 114.4

Note 8. Long-term Borrowings

The components of borrowings were as follows:

(In millions)	January 1, 2023	January 2, 2022
Term Loan	$ 2,646.9	$ —
Revolving Credit Facility	—	—
Financing lease obligation	0.8	0.7
Other long-term borrowings	1.2	—
Unamortized deferred financing costs	(10.6)	—
Total borrowings	2,638.3	0.7
Less: current portion	(207.5)	(0.3)
Long-term borrowings	$ 2,430.8	$ 0.4

On May 27, 2022, the Company entered into a credit agreement (the "Credit Agreement") by and among the Company, as borrower, Bank of America, N.A., as administrative agent and swing line lender ("Bank of America"), and the other lenders and L/C issuers party thereto (together with Bank of America, the "Lenders"). Pursuant to the Credit Agreement and in connection with the consummation of the Combinations, the Lenders provided the Company with a $2,750.0 million senior secured term loan facility (the "Term Loan") and a $750.0 million revolving credit facility (the "Revolving Credit Facility" and with the Term Loan, the "Financing"). Effective August 4, 2022, pursuant to the Increase Joinder No. 1 to the Credit Agreement, the Revolving Credit Facility increased by $50.0 million to $800.0 million. The Financing 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. Loans under the Credit Agreement will bear interest at a rate per annum equal to the Term SOFR or Base Rate plus the Applicable Rate (each as defined in the Credit Agreement). As of January 1, 2023, letters of credit issued under the Revolving Credit Facility totaled $13.1 million, which reduced the available amount under the Revolving Credit Facility to $786.9 million. In connection with the Credit Agreement, the Company incurred $15.4 million of debt issuance costs, of which $11.9 million was related to the Term Loan and $3.5 million was related to the Revolving Credit Facility. Debt issuance costs related to the issuance of the Term Loan were recorded as a reduction of the principal amount of the borrowings and are amortized using the effective interest method as a component of Interest expense, net over the life of the Term Loan. Debt issuance costs related to the Revolving Credit Facility were recorded as Other assets and are amortized on a straight-line basis over the term of the Revolving Credit Facility.

The Term Loan is subject to quarterly amortization of the principal amount on the last business day of each fiscal quarter of the Company (commencing on September 30, 2022). The required quarterly payments are 1.875% of the aggregate initial principal amount of the Term Loan through the fiscal second quarter of 2024, and 1.250% thereafter. The final remaining principal installment is due on the maturity date. The Term Loan and the Revolving Credit Facility will mature on May 27, 2027. The Company must prepay loans outstanding under the Credit Agreement in an amount equal to the Net Cash Proceeds (as defined in the Credit Agreement) from (i) certain property dispositions and (ii) the receipt of certain other amounts not in the ordinary course of business, such as certain insurance proceeds and condemnation awards, in each case, if not reinvested within a specified time period as contemplated in the Credit Agreement.

The Credit Agreement 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, investments and transactions with affiliates. The Credit Agreement contains two financial covenants: (i) a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) as of the last day of each fiscal quarter of (a) 4.50 to 1.00 for the first four fiscal quarters ending after the closing date of the Credit Agreement (the "Initial Measurement Period"), (b) 4.00 to 1.00 for the first four fiscal quarters ending after the Initial Measurement Period and (c) 3.50 to 1.00 for each fiscal quarter thereafter; and (ii) a minimum Consolidated Interest Coverage Ratio (as defined in the Credit Agreement) of 3.00 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 the financial covenants as of January 1, 2023.

The Credit Agreement was entered into in connection with the Combinations in order to fund a portion of the cash portion of the purchase price as well as to repay substantially all of Ortho's then-outstanding indebtedness. See Note 2 for more information regarding the Combinations. In connection with the closing of the Combinations, Quidel terminated its previous $175.0 million revolving credit facility and related credit agreement on May 27, 2022, which did not have an outstanding balance.

The following table provides the detailed amounts within Interest expense, net for fiscal years 2022, 2021 and 2020.

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Term Loan	$ 73.0	$ —	$ —
Revolving Credit Facility	1.5	0.3	0.3
Amortization of deferred financing costs	2.1	0.4	0.4
Derivative instruments and other	0.4	5.4	7.9
Interest income	(1.3)	(0.3)	(0.1)
Interest expense, net	$ 75.7	$ 5.8	$ 8.5

The following table provides a schedule of required future repayments of all borrowings outstanding as of January 1, 2023.

(In millions)	
2023	$ 207.5
2024	172.7
2025	137.5
2026	137.5
2027	1,993.7
Total	$ 2,648.9

Note 9. Leases

The Company leases administrative, R&D, 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.

Operating lease cost for fiscal years 2022, 2021 and 2020 was $26.4 million, $15.4 million and $11.2 million, respectively. Variable lease cost for fiscal years 2022, 2021 and 2020 was $5.6 million, $2.7 million and $1.8 million, respectively. Finance leases are immaterial to the Company's Consolidated Financial Statements.

The supplemental cash flow information related to operating leases during the respective periods was as follows:

	Fiscal Year Ended		
(In millions)	**2022**	**2021**	**2020**
Cash paid for amounts included in the measurement of operating lease liabilities	$ 25.2	$ 12.3	$ 10.8
ROU assets obtained in exchange for new lease liabilities	$ 29.9	$ 37.3	$ 15.3

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable operating leases at the end of 2022 were as follows:

(In millions)		
2023	$	32.7
2024		29.1
2025		26.4
2026		24.1
2027		21.3
Thereafter		122.9
Total lease payments		256.5
Less: imputed interest		(45.7)
Total		210.8
Less: current portion		(24.4)
Non-current portion	$	186.4

Weighted average remaining lease term	9.7 years
Weighted average discount rate	4 %

Summers Ridge Lease — The Company leases 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 must-take provisions related to the fourth building became effective in November 2022 upon expiration of the previous tenant's lease. As a result, the Company recorded a ROU asset and a corresponding lease liability of approximately $20.6 million in November 2022.

Note 10. Stockholders' Equity

Preferred Stock

The Company's Charter 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. No shares of preferred stock were outstanding for fiscal years 2022, 2021 or 2020.

Equity Incentive Plan

In connection with the Combinations, the Company assumed Quidel's 2018 Equity Incentive Plan, as amended and restated (the "Quidel Equity Plan"), including all form of award agreements and grants of awards issued thereunder, and shares of Quidel's common stock ("Quidel Shares") subject to the plan were replaced by an equivalent number of shares of QuidelOrtho's common stock. In connection with the assumption of the Quidel Equity Plan, the Quidel Equity Plan was renamed the "QuidelOrtho Corporation Amended and Restated 2018 Equity Incentive Plan" (the "2018 Plan") and all references to the "Company" in the Quidel Equity Plan were changed to QuidelOrtho. Also in connection with the Combinations, the Company assumed all obligations of Quidel pursuant to each stock option to purchase a Quidel Share and pursuant to each right to acquire or vest in a Quidel Share that was outstanding immediately prior to the closing of the Combinations, and all agreements relating to such equity awards.

The Company grants stock options, time-based RSUs and performance-based RSUs ("PSUs") to employees and non-employee directors under the 2018 Plan. Quidel previously granted stock options under its 2016 Equity Incentive Plan (the "2016 Plan"), Amended and Restated 2010 Equity Incentive Plan (the "2010 Plan") and 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 Quidel Equity 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 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 January 1, 2023, approximately 2.3 million shares of common stock remained available for grant and 4.1 million shares of common stock were reserved for future issuance under the 2018 Plan.

RSUs

The Company grants both RSUs and PSUs to certain officers and directors. Until the restrictions lapse, ownership of the shares underlying the affected RSUs or PSUs is conditional upon continuous employment with the Company and/or achievement of certain performance goals.

For fiscal years 2022, 2021 and 2020, the Company granted approximately 0.7 million, 0.1 million and 0.2 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 fiscal years 2022, 2021 and 2020, 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, $0.6 million and $0.5 million for fiscal years 2022, 2021 and 2020, respectively.

Employee Deferred Bonus Compensation Program

For fiscal years 2022, 2021 and 2020, 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 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 is 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

In connection with the Combinations, the Company assumed Quidel's 1983 Employee Stock Purchase Plan, as amended and restated (the "Quidel ESPP"), and the Quidel Shares subject to the Quidel ESPP were replaced by an equivalent number of shares of QuidelOrtho's common stock. In connection with the assumption of the Quidel ESPP, the Quidel ESPP was renamed the "QuidelOrtho Corporation Amended and Restated 1983 Employee Stock Purchase Plan" (the ESPP) and all references to the "Company" in the Quidel ESPP were changed to QuidelOrtho.

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 January 1, 2023, 736,630 shares of common stock remained available for future issuance.

Stock Repurchase Program

On December 18, 2018, Quidel announced a stock repurchase program to repurchase up to $50.0 million of its common stock, which was authorized by Quidel's board of directors (the "Quidel Board") on December 12, 2018. On August 28, 2020, the Board authorized an increase of an additional $150.0 million to Quidel'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. In connection with the consummation of the Combinations, Quidel's stock repurchase program was terminated. On August 17, 2022, the Board authorized a stock repurchase program, allowing the Company to repurchase up to $300.0 million of its common stock through August 17, 2024 (the "Stock Repurchase Program").

During fiscal year 2022, 953,468 shares of outstanding common stock were repurchased under the Stock Repurchase Program. As of January 1, 2023, the Company had approximately $225.7 million available under the Stock Repurchase Program. During fiscal years 2021 and 2020, 957,239 and 257,329 shares of outstanding common stock were repurchased under Quidel's stock repurchase program.

Note 11. Stock-based Compensation

Stock-based compensation expense was as follows:

	Fiscal Year Ended		
(In millions)	2022	2021	2020
Cost of sales	$ 2.9	$ 2.7	$ 2.0
Research and development	4.9	4.4	3.4
Selling, marketing and administrative	27.4	18.3	15.6
Acquisition and integration costs	30.4	—	—
Total stock-based compensation expense	$ 65.6	$ 25.4	$ 21.0

The table above includes $17.2 million of compensation expense related to liability-classified awards for fiscal year 2022, which has been or is expected to be settled in cash. These awards represent the $7.14 per share cash settled portion of the replacement awards issued in connection with the Combinations.

For fiscal years 2022, 2021 and 2020, the Company recorded $3.7 million, $3.0 million and $2.2 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program, described in Note 10. During fiscal years 2022, 2021 and 2020, $3.3 million, $2.8 million and $2.1 million, respectively, were initially recorded as a component of accrued payroll and related expenses associated with the deferred bonus compensation program.

Stock Options

A summary of the status of stock option activity for fiscal year 2022 is as follows:

(In thousands, except price data)	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at January 2, 2022	722	$ 62.71		
Granted	187	100.45		
Stock options assumed in the Combinations	1,229	96.10		
Exercised	(383)	55.15		
Forfeited	(99)	115.95		
Outstanding at January 1, 2023	1,656	$ 90.34	5.53	$ 28,140
Vested and expected to vest at January 1, 2023	1,600	$ 89.23	5.45	$ 28,122
Exercisable at January 1, 2023	1,195	$ 80.53	4.61	$ 26,774

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 for the option grants, including grants related to options assumed in the Combinations presented separately:

	Assumed on	Fiscal Year Ended		
	May 27, 2022 [1]	January 1, 2023	January 2, 2022	January 3, 2021
Risk-free interest rate	2.28 %	1.96 %	0.48 %	1.18 %
Expected option life (in years)	1.78	4.80	4.99	5.12
Volatility rate	64 %	57 %	54 %	41 %
Dividend rate	0 %	0 %	0 %	0 %
Weighted-average grant date fair value	$40.57	$50.62	$106.55	$36.84

(1) The replacement stock options granted to Ortho option holders on the closing date of the Combinations were issued consistent with the vesting conditions of the replaced award. The fair value on the closing date of the Combinations attributed to post-combination service, adjusted for estimated forfeitures, is recognized as expensed on a straight-line basis over the remaining vesting period.

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 total intrinsic value was $13.7 million, $9.9 million and $51.8 million for options exercised during fiscal years 2022, 2021, and 2020, respectively. As of January 1, 2023, total unrecognized compensation expense related to stock options was approximately $27.2 million and the related weighted-average period over which it is expected to be recognized is approximately 3.4 years. The maximum contractual term of the Company's stock options is ten years.

RSUs

A summary of the status of RSU activity for fiscal year 2022 is as follows:

(In thousands, except price data)	Shares	Weighted-Average Grant Date Fair Value
Non-vested at January 2, 2022	587	$ 95.81
Granted	720	97.31
Stock awards assumed in the Combinations	49	99.60
Vested	(248)	86.61
Forfeited	(76)	100.70
Non-vested at January 1, 2023	1,032	$ 98.89

The total amount of unrecognized compensation expense related to non-vested RSUs as of January 1, 2023 was approximately $62.7 million, which is expected to be recognized over a weighted-average period of approximately 2.1 years.

The fair value of RSUs is determined based on the closing market price of the Company's common stock on the grant date. The weighted-average fair value of RSUs granted during the fiscal years ended January 2, 2022 and January 3, 2021 was $188.06 and $101.20, respectively.

Note 12. Commitments and Contingencies

Purchase Obligations

The Company had $247.8 million of purchase obligations as of January 1, 2023, the majority of which is expected to be purchased in the next year. These purchase obligations include agreements to purchase goods or services that are enforceable and legally binding and that specify all significant terms, including (i) fixed or minimum quantities to be purchased, (ii) fixed, minimum or variable price provisions and (iii) the approximate timing of the transaction, as well as amounts for planned inventory purchases under contractual arrangements.

Litigation and Other Legal Proceedings

From time to time, the Company is involved in litigation and other 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. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded. Estimates of probable losses resulting from these matters are inherently difficult to predict. 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 January 1, 2023 and January 2, 2022 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.

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 $1.1 million, $2.0 million and $2.4 million for fiscal years 2022, 2021 and 2020, respectively.

Note 13. Fair Value Measurements

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:

	January 1, 2023				January 2, 2022			
(In millions)	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents	$ 0.6	$ 2.1	$ —	$ 2.7	$ 204.7	$ 6.6	$ —	$ 211.3
Marketable securities	2.0	71.1	—	73.1	—	63.6	—	63.6
Derivative assets	—	22.0	—	22.0	—	0.1	—	0.1
Total assets measured at fair value	$ 2.6	$ 95.2	$ —	$ 97.8	$ 204.7	$ 70.3	$ —	$ 275.0
Liabilities:								
Derivative liabilities	$ —	$ 21.8	$ —	$ 21.8	$ —	$ 0.3	$ —	$ 0.3
Contingent consideration	—	—	0.1	0.1	—	—	6.1	6.1
Deferred consideration	—	39.3	—	39.3	—	78.4	—	78.4
Total liabilities measured at fair value	$ —	$ 61.1	$ 0.1	$ 61.2	$ —	$ 78.7	$ 6.1	$ 84.8

There were no transfers of assets or liabilities into or out of Level 3 of the fair value hierarchy during fiscal years 2022 and 2021.

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 and government debt securities, corporate asset-backed securities and commercial paper. 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 from Alere Inc., the Company will pay annual installments of up to $48.0 million each year through April 2023. The fair value of the payments treated as 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 payments treated as contingent consideration is calculated using a discounted probability weighted valuation model. Discount rates used in such calculations are significant assumptions that are not observed in the market and, therefore, the resulting fair value represents a Level 3 measurement.

Changes in estimated fair value of contingent consideration liabilities from January 3, 2021 through January 1, 2023 were as follows:

(In millions)	Contingent Consideration Liabilities (Level 3 Measurement)
Balance at January 3, 2021	$ 11.9
Cash payments	(6.0)
Change in estimated fair value, recorded in selling, marketing and administrative expenses	0.2
Balance at January 2, 2022	$ 6.1
Cash payments	(6.0)
Balance at January 1, 2023	$ 0.1

Financial Instruments Not Measured at Fair Value

The estimated fair value of the Company's borrowings under the Term Loan was $2,630.3 million at January 1, 2023, compared to the carrying amount, excluding debt issuance costs, of $2,646.9 million. The estimate of fair value is generally based on the quoted market prices for similar issuances of long-term debt with the same maturities, which is classified as a Level 2 input.

Note 14. Derivative Instruments and Hedging Activities

The Company selectively uses derivative and non-derivative instruments to manage market risk associated with changes in interest rates and foreign currency exchange rates. The use of derivatives is intended for hedging purposes only, and the Company does not enter into derivative transactions for speculative purposes.

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. The Company generally enters into master netting arrangements that reduce credit risk by permitting net settlement of transactions with the same counterparty. The Company does not have any derivative instruments with credit-risk related contingent features that would require it to post collateral.

Interest Rate Hedging Instruments

The Company's interest rate risk relates primarily to interest rate exposures on variable rate debt, including the Revolving Credit Facility and Term Loan. See Note 8 for additional information on the currently outstanding components of the Revolving Credit Facility and Term Loan. The Company entered into interest rate cap and swap agreements to hedge the related risk of the variability to the Company's cash flows due to the rates specified for these credit facilities.

The Company designates certain interest rate derivative instruments as cash flow hedges, including the outstanding interest rate swaps. The Company records gains and losses due to changes in fair value of the derivatives within Other comprehensive income (loss) ("OCI") and reclassifies these amounts to Interest expense, net in the same period or periods for which the underlying hedged transaction affects earnings. In the event the Company determines the hedged transaction is no longer probable to occur or concludes the hedge relationship is no longer effective, the hedge is prospectively de-designated. Pre-tax unrealized gains of $25.1 million are expected to be reclassified from OCI to earnings in the next 12 months.

The following table summarizes the Company's interest rate derivative agreements as of January 1, 2023, all of which were interest rate swaps:

Notional Amount (In millions) [1]	Description	Hedge Designation	Effective Date	Expiration Date
$ 500.0	Pay 1.58% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	May 29, 2022	December 31, 2023
397.2	Pay 3.765% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
144.4	Pay 3.7725% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
216.7	Pay 3.7675% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
288.9	Pay 3.7575% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
252.8	Pay 3.7725% fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027

(1) The notional value of interest rate swap contracts with an effective date of December 30, 2022, is expected to increase to $1.8 billion on December 29, 2023.

During the fourth quarter of 2022, the Company terminated its non-designated $1.0 billion notional value 3.428% interest rate cap. As a result of this termination in fiscal year 2022, the Company recognized an immaterial gain within Other expense (income), net and received $3.3 million of cash proceeds, presented within operating activities in the Consolidated Statements of Cash Flows.

Currency Hedging Instruments

The Company has currency risk exposures relating primarily to foreign currency denominated monetary assets and liabilities and forecasted foreign currency denominated intercompany and third-party transactions. The Company uses foreign currency forward contracts and may use option contracts and cross currency swaps to manage its currency risk exposures. The Company's foreign currency forward contracts are denominated primarily in Australian Dollar, Brazilian Real, British Pound, Canadian Dollar, Chilean Peso, Chinese Yuan/Renminbi, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Swiss Franc and the Thai Baht.

The Company designates certain foreign currency forward contracts as cash flow hedges. The Company records gains and losses due to changes in fair value of the derivatives within OCI and reclassifies these amounts to Total revenues and Cost of

sales, excluding amortization of intangibles in the same period or periods for which the underlying hedged transaction affects earnings. In the event the Company determines the hedged transaction is no longer probable to occur or concludes the hedge relationship is no longer effective, the hedge is prospectively de-designated. The pre-tax unrealized loss of $7.9 million within OCI as of January 1, 2023 is expected to be reclassified to earnings in the next 12 months.

The Company also enters into foreign currency forward contracts that are not part of designated hedging relationships and which are intended to mitigate exchange rate risk of monetary assets and liabilities and related forecasted transactions. The Company records these non-designated derivatives at mark-to-market with gains and losses recognized in earnings within Other expense (income), net.

The following table provides details of the currency hedging instruments outstanding as of January 1, 2023:

Description	Notional Amount (In millions)	Hedge Designation
Foreign currency forward contracts	$ 441.6	Cash Flow Hedge
Foreign currency forward contracts	581.7	Non-designated

The following table summarizes pre-tax gains and losses from designated derivative and non-derivative instruments within accumulated other comprehensive (loss) income ("AOCI") for fiscal year 2022:

	Designated Hedging Instruments		
(In millions)	Amount of Loss (Gain) Recognized in OCI on Hedges	Location of Amounts Reclassified From AOCI Into Income	Amount of Loss (Gain) Reclassified From AOCI Into Income
Foreign currency forward contracts (sales)	$ 1.3	Total revenues	$ (2.9)
Foreign currency forward contracts (purchases)	3.5	Cost of sales, excluding amortization of intangibles	(0.6)
Interest rate derivatives	(11.4)	Interest expense, net	(1.7)

Gains and losses from designated derivative and non-derivative instruments within AOCI for fiscal years 2021 and 2020 were not material.

The following table summarizes the fair value of designated and non-designated hedging instruments recognized within the Consolidated Balance Sheets as of January 1, 2023 and January 2, 2022:

(In millions)	January 1, 2023	January 2, 2022
Designated cash flow hedges		
Interest rate derivatives:		
Prepaid expenses and other current assets	$ 15.9	$ —
Other liabilities	2.1	—
Foreign currency forward contracts:		
Prepaid expenses and other current assets	4.6	0.1
Other current liabilities	14.3	0.2
Non-designated hedging instruments		
Foreign currency forward contracts:		
Prepaid expenses and other current assets	1.5	—
Other current liabilities	5.4	0.1

Note 15. Long-term Employee Benefits

Defined Benefit Plans and Other Post-employment Benefits

In connection with the Combinations, the Company assumed certain defined benefit plan obligations and acquired related plan assets for employees of non-U.S. subsidiaries.

In addition to these defined benefit plans, the Company also assumed one non-U.S. post-employment benefit plan and a replacement retiree health care reimbursement plan for certain U.S employees. The U.S. plan is funded on a pay-as-you-go basis and is not accepting new participants.

Obligation and Funded Status

The measurement date used to determine the defined benefit and other post-employment benefits obligations was January 1, 2023. The following tables set forth the changes to the projected benefit obligations ("PBO") and plan assets:

(In millions)	Fiscal Year Ended January 1, 2023
Defined Benefit Plans	
Change in benefit obligation:	
Projected benefit obligation at beginning of year	$ —
Service cost	1.2
Interest cost	0.4
Benefits paid	(0.3)
Actuarial gain	(0.6)
Assumed obligation from the Combinations	33.3
Settlements	(0.2)
Foreign currency exchange rate changes	0.1
Projected benefit obligation at end of year	$ 33.9
Change in plan assets:	
Fair value of plan assets at beginning of year	$ —
Actual return on plan assets	(0.5)
Employer contributions	1.6
Benefits paid	(0.3)
Transfers in from the Combinations	20.1
Settlements	(0.2)
Foreign currency exchange rate changes	(0.1)
Fair value of plan assets at end of year	$ 20.6
Funded status at end of year	$ (13.3)
Amounts recognized on the consolidated balance sheets:	
Other assets	$ 0.4
Other current liabilities	(0.3)
Other liabilities	(13.4)
Net amount recognized	$ (13.3)

(In millions)	Fiscal Year Ended January 1, 2023
Other Post-employment Benefits	
Change in benefit obligation:	
Projected benefit obligation at beginning of year	$ 18.9
Service cost	0.3
Interest cost	0.4
Benefits paid	(0.7)
Actuarial gain	(0.7)
Assumed obligation from the Combinations	0.4
Projected benefit obligation at end of year	$ 18.6
Amounts recognized on the consolidated balance sheets:	
Other current liabilities	$ (3.5)
Other liabilities	(15.1)
Net amount recognized	$ (18.6)

PBO is the actuarial present value of benefits attributable to employee service rendered to date and reflects the effects of estimated future pay increases. The accumulated benefit obligation ("ABO") is the actuarial present value of benefits attributable to employee service to date, but does not include the effects of estimated future pay increases.

The following table reflects the ABO for all defined benefit plans as of January 1, 2023. Further, the table reflects the aggregate PBO, ABO and fair value of plan assets for pension plans with PBO in excess of plan assets and for pension plans with ABO in excess of plan assets.

(In millions)	January 1, 2023
ABO	$ 27.1
Plans with PBO in excess of plan assets	
PBO	$ 18.3
Fair value of plan assets	5.1
Plans with ABO in excess of plan assets	
PBO	$ 17.0
ABO	14.3
Fair value of plan assets	3.8

The pretax amounts that are not yet reflected in the net periodic benefit cost and are included in AOCI as of January 1, 2023 include the following:

(In millions)	Fiscal Year Ended 2022
Defined Benefit Plans	
Accumulated net actuarial gains (losses)	$ (0.2)
Other Post-employment Benefits	
Accumulated net actuarial gains (losses)	$ 0.7

These accumulated net actuarial gains (losses) for defined benefit plans and other post-employment benefits primarily relate to differences between the actual net periodic expense and the expected net periodic expense from differences in significant assumptions, including primarily return on plan assets and discount rates used in these estimates.

Components of Net Periodic Benefit Cost

Net periodic benefit cost for the Company's defined benefit plans was $1.4 million for the fiscal year ended January 1, 2023 and was primarily related to service cost. Changes in plan assets and benefit obligations recognized in other comprehensive income was not material for fiscal year 2022.

Net periodic benefit cost for the Company's other post-employment benefit plans was $0.7 million for the fiscal year ended January 1, 2023 and was primarily related to interest cost. Changes in benefit obligations recognized in other comprehensive income was not material for fiscal year 2022.

The components of net periodic benefit cost other than the service cost component are recorded in Other expense (income), net in the Consolidated Statements of Income.

Assumptions and Sensitivities

In connection with the preliminary purchase price allocation for the Combinations, the Company recorded assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The following assumptions were used to measure the fair value of the benefit obligations and associated plan assets:

	May 27, 2022	January 1, 2023
Defined Benefit Plans		
Weighted average discount rate	2.2 %	3.1 %
Weighted average rate of compensation increases	2.6 %	3.0 %
Other Post-employment Benefit Plans		
Weighted average discount rate	4.0 %	5.5 %

The critical assumptions used in determining the net periodic benefit cost for fiscal year 2022 are as follows:

Defined Benefit Plans	
Weighted average discount rate	2.2 %
Weighted average expected rate of compensation increases	2.6 %
Weighted average expected return on plan assets	2.5 %
Other Post-employment Benefit Plans	
Weighted average discount rate	4.0 %

The discount rates used reflect the expected future cash flow based on plan provisions, participant data and the currencies in which the expected future cash flows will occur. For the majority of defined benefit obligations, the Company utilizes prevailing long-term high quality corporate bond indices applicable to the respective country at the measurement date. In countries where established corporate bond markets do not exist, the Company utilizes other index movement and duration analysis to determine discount rates. The long-term rate of return on plan assets assumptions reflect economic assumptions applicable to each country and assumptions related to the preliminary assessments regarding the type of investments to be held by the respective plans.

The discount rate is determined as of each measurement date, based on a review of yield rates associated with long-term, high-quality corporate bonds. The calculation separately discounts benefit payments using the spot rates from a long-term, high-quality corporate bond yield curve.

The long-term rate of return on plan assets assumption represents the expected average rate of earnings on the funds invested to provide for the benefits included in the benefit obligations and is determined based on a number of factors, including historical market index returns, the anticipated long-term allocation of the plans, historical plan return data, plan expenses and the potential to outperform market index returns.

A significant factor in estimating future per capita cost of covered healthcare benefits for retirees is the healthcare cost trend rate assumption. The health care cost trend rate assumptions for other post-retirement benefit plans are as follows:

	January 1, 2023
Health care cost trend rate assumed for next year - Pre-65	6.44 %
Health care cost trend rate assumed for next year - Post-65	6.10 %
Rate to which the cost trend rate is assumed to decline	4.00 %
Year that the trend rate reaches the ultimate trend rate	2047

Anticipated Contributions to Defined Benefit Plans

For funded plans, our policy is to fund amounts for defined benefit plans sufficient to meet minimum requirements set forth in applicable benefit and local tax laws. Based on the same assumptions used to measure the defined benefit obligations at January 1, 2023, the Company expects to contribute $2.0 million to defined benefit plans in fiscal year 2023.

Estimated Future Benefit Payments

The following table reflects the total benefit payments expected to be made for defined benefit plans and other long-term post-employment benefits:

(In millions)	Defined Benefit Plans	Other Post-employment Benefit Plans
Fiscal Year 2023	$ 1.7	$ 3.5
Fiscal Year 2024	3.5	4.0
Fiscal Year 2025	2.1	3.3
Fiscal Year 2026	2.2	2.2
Fiscal Year 2027	2.3	1.9
Fiscal Years 2028-2032	12.6	5.5

Plan Assets

The tables below present the fair value of the defined benefit pension plans by level within the fair value hierarchy, as described in Note 1, at January 1, 2023.

	Fair Value Measurements at January 1, 2023			
(In millions)	Total	Level 1	Level 2	Level 3
U.S. equity securities	$ 2.2	$ 2.2	$ —	$ —
Japan equity securities	3.7	3.7	—	—
Other international equity securities	1.6	1.6	—	—
U.S. government bonds	0.2	0.2	—	—
Japan government bonds	0.5	0.5	—	—
Other international government bonds	1.6	1.6	—	—
Cash and cash equivalents	4.7	4.7	—	—
Insurance contracts	6.1	—	—	6.1
Total	$ 20.6	$ 14.5	$ —	$ 6.1

The Company has funded defined benefit plans in Japan, Belgium and Switzerland. The Japanese plan asset consists primarily of Japan equity and government bond securities, U.S. equity and government bond securities, other international equity and debt securities and cash and cash equivalents. The plan assets are invested in assets with quoted prices in active markets and therefore are classified as Level 1 assets. The Company's investment strategy is to maintain a target rate of return that is higher than that required to maintain sound pension plan management into the future. In order to achieve its investment targets, the Company has established an asset composition ratio which was formulated from a long-term perspective, taking into account the maturity of the pension plan and other factors. The Company considers expected returns and risks of returns, as well as the correlation between the returns of each investment asset, the diversification of its investments, and other factors related to risk management in order to maximize returns in accordance with its targeted asset mix to achieve its investment targets. The target

allocation rates of the Japanese plan is 44% for debt securities, 55% for equity securities and 2% for other assets. The Belgium and Switzerland plan assets consist solely of insurance contracts that are pledged on behalf of employees with benefits in certain countries and are classified as Level 3 assets.

The table below presents a roll-forward of activity for the Level 3 assets for fiscal year 2022:

(In millions)	Level 3 Assets
Balance at January 2, 2022	$ —
Transfers in	5.5
Net purchases and settlements	0.6
Balance at January 1, 2023	$ 6.1

Defined Contribution Plans

The Company offers defined contribution plans to eligible employees primarily in the U.S., whereby employees contribute a portion of their compensation. Company matching and other Company contributions are also provided to the plans. Once Company matching contributions have been paid, the Company has no further payment obligations. The Company's contributions for its employees totaled approximately $15.1 million, $3.8 million and $3.1 million for fiscal years ended 2022, 2021 and 2020, respectively, which are recognized as expense as incurred in the Consolidated Statements of Income. The increase in Company contributions for fiscal year 2022 was due to defined contribution plans assumed in connection with the Combinations.

Note 16. Related Party Transactions

Quotient Limited

As a result of the consummation of the Combinations, the Company acquired Ortho's Letter Agreement (the "Letter Agreement"), entered into in September 2020, with Quotient Limited ("Quotient"), in which Ortho partnered with Quotient to commercialize, when approved, the next generation product in immunohematology, a transfusion diagnostic patient immunohematology microarray intended for use with Quotient's MosaiQ instruments (the "IH3 Microarray") that enables a high level of multiplexing and addresses the ultra-high throughput market. Under the Letter Agreement, Ortho will have the right to distribute, market and sell the IH3 Microarrays in the European Economic Area, the U.K. and Switzerland (collectively, the "European Territory") and the U.S., solely for use in testing the immunohematological profile of the blood of medical patients in the course of their care or treatment. Quotient retains the right to distribute, market and sell the IH3 Microarrays for use in blood donor testing worldwide and in the patient testing market outside of the European Territory and the U.S. Ortho's rights with respect to the IH3 Microarray are exclusive so long as Ortho satisfies its obligation to meet annual minimum purchase volume requirements in each territory. Under the Letter Agreement, Ortho also has the non-exclusive right to sell and distribute MosaiQ instruments in the U.S. and the European Territory for use in testing the immunohematological profile of blood of medical patients in the course of their care or treatment.

Under the Letter Agreement, Ortho is also required to purchase the IH3 Microarrays, and the instruments, controls and reagents required for their use, only from Quotient at specified prices. Ortho is also required to make milestone payments to Quotient as specified milestones and benchmarks are achieved. Ortho will be obligated to pay up to $60 million in milestone payments to Quotient upon its achievement of certain regulatory milestones and the achievement by Ortho of commercial sales benchmarks related to MosaiQ, including a milestone payment of up to $25 million upon the achievement by Ortho of certain cumulative gross revenue hurdles. The Company did not make such payments during fiscal year 2022. Due to the Company's equity method investment held in Quotient, the Company concluded that Quotient is a related party of the Company.

On January 10, 2023, Quotient filed a voluntary petition for relief under chapter 11 of title 11 of the United States Code in the United States Bankruptcy Court for the Southern District of Texas (the "Bankruptcy Proceeding"). The Company is evaluating the impact of the Bankruptcy Proceeding and the related changes in Quotient's business strategy on the Letter Agreement.

Under a separate supply agreement between Ortho and Alba Biosciences, a wholly owned subsidiary of Quotient, which was also acquired by the Company as a result of the consummation of the Combinations, the Company purchased inventories from Alba Biosciences amounting to $15.4 million during fiscal year 2022. As of January 1, 2023, Accounts payable included amounts related to purchases from Alba Biosciences of $3.7 million. Quotient has stated that none of its subsidiaries intend to file voluntary petitions for relief under the Bankruptcy Code, and that each of its subsidiaries expects to continue to operate its respective business in the ordinary course unaffected by the Bankruptcy Proceeding. The Company will continue to monitor the situation.

Note 17. Accumulated Other Comprehensive Income (Loss)

The balance of AOCI, net of tax, was as follows for fiscal year 2022:

(In millions)	Pension and Other Post-employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Income (Loss)
Beginning balance	$ —	$ —	$ (0.1)	$ 0.5	$ 0.4
Current period deferrals	0.7	6.7	(0.4)	(69.8)	(62.8)
Amounts reclassified to net income	—	(5.2)	—	—	(5.2)
Net change	0.7	1.5	(0.4)	(69.8)	(68.0)
Ending balance	$ 0.7	$ 1.5	$ (0.5)	$ (69.3)	$ (67.6)

Amounts related to fiscal years 2021 and 2020 were not material.

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 Exchange Act Rules 13a-15(e) and 15d-15(e). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of January 1, 2023 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 rules and forms of the SEC. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Changes in internal control over financial reporting: As of January 1, 2023, management is in the process of integrating the internal controls of the acquired Ortho business into our existing operations as part of planned integration activities. There were no other changes in our internal control over financial reporting during the fiscal quarter ended January 1, 2023 that materially affected, or are 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 terms are defined in Exchange Act Rules 13a-15(f) and 15d-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 January 1, 2023.

In accordance with SEC guidance, we have excluded from the scope of our assessment of internal control over financial reporting the operations and related assets of Ortho, which we acquired on May 27, 2022. At January 1, 2023 and for the period from acquisition through January 1, 2023, total assets and total revenues subject to Ortho's internal control over financial reporting represented 22% and 36%, respectively, of our consolidated total assets and total revenues as of and for the fiscal year ended January 1, 2023.

The effectiveness of our internal control over financial reporting as of January 1, 2023 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 QuidelOrtho Corporation

Opinion on Internal Control over Financial Reporting

We have audited QuidelOrtho Corporation's internal control over financial reporting as of January 1, 2023, 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, QuidelOrtho Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of January 1, 2023, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Ortho which is included in the 2022 consolidated financial statements of the Company and constituted 22% of total assets as of January 1, 2023 and 36% of revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Ortho.

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 January 1, 2023 and January 2, 2022, the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows, for each of the three years in the period ended January 1, 2023, and the related notes and our report dated February 23, 2023 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 23, 2023

Item 9B. Other Information

Effective on February 22, 2023, the Board approved a change of the Company's registered agent and registered office. The Company filed a Change of Registered Agent and/or Registered Office (the "Certificate of Change") with the Secretary of State of the State of Delaware to change the Company's registered agent to Registered Agent Solutions, Inc. and its registered office to 838 Walker Road, Suite 21-2, Dover, County of Kent, Delaware 19904. The Certificate of Change was approved by the Board in accordance with Delaware law and has the effect of amending Section 2 of the Company's Charter.

A copy of the Certificate of Change is attached as Exhibit 3.3 to this Annual Report and incorporated herein by reference.

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 is incorporated herein by reference to our 2023 proxy statement to be filed with the SEC within 120 days of the year ended January 1, 2023 (the "2023 Proxy Statement"), including under the headings "Board of Directors and Corporate Governance," "Information about our Executive Officers," "Business Ethics and Compliance" and "Delinquent Section 16(a) Reports," if applicable.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our 2023 Proxy Statement, including under the headings "Executive Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report."

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

The information required by this item is incorporated herein by reference to our 2023 Proxy Statement, including under the headings "Securities Available for Issuance under our Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management."

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

The information required by this item is incorporated herein by reference to our 2023 Proxy Statement, including under the headings "Review and Approval of Related Party Transactions," "Related Party Transactions" and "Director Independence."

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our 2023 Proxy Statement, including under the heading "Independent Registered Public Accounting Firm."

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 Annual Report.

(2) Financial Statement Schedules

Financial Statement Schedules 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 Item 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.

(c) Financial Statements required by Regulation S-X which are excluded from this Annual Report 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., Orca Holdco, Inc., Laguna Merger Sub, Inc. and Orca Holdco 2, Inc. (incorporated by reference to Annex A to the joint proxy statement/prospectus forming part of the Registration Statement on Form S-4 filed by Coronado Topco, Inc. with the SEC on January 31, 2022)
3.1	Amended and Restated Certificate of Incorporation of QuidelOrtho Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 27, 2022)
3.2	Amended and Restated Bylaws of QuidelOrtho Corporation (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on December 13, 2022)
3.3*	Certificate of Change of Registered Agent
4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
4.2*	Description of QuidelOrtho Corporation's Securities Registered Pursuant to Section 12 of the Exchange Act of 1934
10.1(1)	Summary of Certain Compensation Arrangements for Executive Officers (incorporated by reference to the Registrant's Form 8-K filed on June 6, 2022)
10.2	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 Annex B to the joint proxy statement/prospectus forming part of the Registration Statement on Form S-4 filed by Coronado Topco, Inc. with the SEC on January 31, 2022)

Exhibit Number	Description
10.3+	Credit Agreement, dated May 27, 2022, by and among QuidelOrtho Corporation, each lender from time to time party thereto, each L/C Issuer (as defined therein), and Bank of America, N.A., as Administrative Agent and Swing Line Lender (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on May 27, 2022)
10.4	Increase Joinder No. 1, dated August 4, 2022, by and among QuidelOrtho Corporation, JPMorgan Chase Bank, N.A., as New Revolving Credit Lender, a Lender and a L/C Issuer, the Guarantors party thereto, and Bank of America, N.A., as the Administrative Agent (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.5(1)	QuidelOrtho Corporation Amended and Restated 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on May 27, 2022)
10.6(1)	Form of Restricted Stock Unit Award Grant Notice (incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.7(1)	Form of Restricted Stock Unit Award Grant Notice (Performance-based) (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.8(1)	Form of Restricted Stock Unit Award Grant Notice (Time-based) (incorporated by reference to Exhibit 10.8 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.9(1)	Form of Restricted Stock Unit Award Grant Notice (Deferred) (incorporated by reference to Exhibit 10.9 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.10(1)	Form of Notice of Grant of Nonqualified Stock Options and Option Agreement (incorporated by reference to Exhibit 10.10 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.11(1)	Form of Phantom Stock Unit Award Grant Notice (incorporated by reference to Exhibit 10.11 to the Registrant's Form 10-Q for the quarter ended July 3, 2022 filed on August 5, 2022)
10.12(1)	QuidelOrtho Corporation Amended and Restated 1983 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on May 27, 2022)
10.13(1)	Employment Agreement, dated January 16, 2009, between Quidel Corporation and Douglas C. Bryant (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by Quidel Corporation with the SEC on January 20, 2009)
10.14(1)	Employment Offer Letter, dated June 5, 2008, between Quidel Corporation and Robert J. Bujarski (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by Quidel Corporation with the SEC on June 6, 2008)
10.15(1)	Employment Offer Letter, dated April 24, 2014, between Quidel Corporation and Werner Kroll (incorporated by reference to Exhibit 10.1 to the Form 10-Q for the quarter ended June 30, 2014 filed by Quidel Corporation with the SEC on July 24, 2014)
10.16(1)	Enhanced Minimum Severance Letter, dated June 30, 2020, between Ortho-Clinical Diagnostics, Inc. and Joseph M. Busky (incorporated by reference to Exhibit 10.19 to the Form S-1 filed by Ortho Clinical Diagnostics Holdings plc with the SEC on January 4, 2021)
10.17(1)	Severance Letter Agreement with Michael Iskra, dated May 2021 (incorporated by reference to Exhibit 99.1 to the Form 8-K filed by Ortho Clinical Diagnostics Holdings plc with the SEC on May 25, 2021)
10.18(1)	Form of Retention/Loyalty Bonus Opportunity Agreement (incorporated by reference to Exhibit 99.1 to the Form 8-K filed by Ortho Clinical Diagnostics Holdings plc with the SEC on January 18, 2022)
10.19(1)	Amended and Restated Special Advisor Agreement, dated April 3, 2022, between Christopher Smith and QuidelOrtho Corporation (incorporated by reference to Exhibit 99.4 to the Form 8-K filed by Ortho Clinical Diagnostics Holdings plc with the SEC on April 7, 2022)
10.20(1)	Letter Agreement, dated April 3, 2022, between Ortho Clinical Diagnostics Holdings plc and Christopher Smith (incorporated by reference to Exhibit 99.3 to the Form 8-K filed by Ortho Clinical Diagnostics Holdings plc with the SEC on April 7, 2022)
10.21(1)	Form of Integration and Retention Bonus Letter (incorporated by reference to Exhibit 10.4 to the Form 8-K filed by Quidel Corporation with the SEC on February 4, 2022)
10.22(1)	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.10 to the Registrant's Form 8-K filed on May 27, 2022)

Exhibit Number	Description
10.23(1)	Form of Change in Control Agreement (incorporated by reference to Exhibit 10.11 to the Registrant's Form 8-K filed on May 27, 2022)
10.24(1)	Individual Retirement Program for Werner Kroll (incorporated by reference to Exhibit 10.3 to the Form 8-K filed by Quidel Corporation with the SEC on February 4, 2020)
10.25	Summers Ridge Lease (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by Quidel Corporation with the SEC on January 9, 2018)
10.26	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 Form 8-K filed by Quidel Corporation on July 26, 2021)
21.1*	Subsidiaries of QuidelOrtho Corporation
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification by Principal Executive Officer of QuidelOrtho Corporation 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 Officer of QuidelOrtho Corporation 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 Officer of QuidelOrtho Corporation 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 January 1, 2023, 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 January 1, 2023, formatted in Inline XBRL (included as Exhibit 101).

* Filed herewith.

** Furnished herewith.

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

+ Certain identified information has been omitted by means of marking such information with asterisks in reliance on Items 601(b)(2)(ii) and 601(b)(10)(iv) of Regulation S-K, as applicable, because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

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.

QUIDELORTHO CORPORATION

By /s/ DOUGLAS C. BRYANT

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

Date: February 23, 2023

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 and Chief Executive Officer (Principal Executive Officer)	February 23, 2023
/s/ JOSEPH M. BUSKY Joseph M. Busky	Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2023
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 23, 2023
/s/ EVELYN S. DILSAVER Evelyn S. Dilsaver	Director	February 23, 2023
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 23, 2023
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 23, 2023
/s/ ANN D. RHOADS Ann D. Rhoads	Director	February 23, 2023
/s/ ROBERT R. SCHMIDT Robert R. Schmidt	Director	February 23, 2023
/s/ CHRISTOPHER M. SMITH Christopher M. Smith	Director	February 23, 2023
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 23, 2023
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 23, 2023
/s/ JOSEPH D. WILKINS JR. Joseph D. Wilkins Jr.	Director	February 23, 2023
/s/ STEPHEN H. WISE Stephen H. Wise	Director	February 23, 2023

[This page intentionally left blank]

Board of Directors

Douglas C. Bryant
President and Chief Executive Officer
of QuidelOrtho Corporation

Kenneth F. Buechler, PhD
Chairman of QuidelOrtho Corporation
Founder and Former President and Chief Scientific Officer
of Biosite, Inc.

Evelyn S. Dilsaver
Former President and Chief Executive Officer
of Charles Schwab Investment Management

Edward L. Michael
Managing Partner and Co-Founder of LionBird Ventures
Former Executive Vice President of Diagnostic Products
at Abbott Laboratories

Mary Lake Polan, MD, PhD, MPH
Professor of Clinical Obstetrics, Gynecology and
Reproductive Sciences, Yale University School of Medicine

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

Robert R. Schmidt
Managing Director of The Carlyle Group

Christopher M. Smith
Chief Executive Officer of Neogenomics, Inc.
Former Chief Executive Officer and Chairman of the
Board of Ortho Clinical Diagnostics Holdings Plc

Matthew W. Strobeck, PhD
Managing Partner of Birchview Capital

Kenneth J. Widder, MD
Former Chief Executive Officer of Sydnexis Inc.

Joseph D. Wilkins Jr.
Senior Advisor for THEO Executive Group
Managing Director of JW Healthcare Insights
Former Executive of Atlantic Health System,
Quest Diagnostics and Danaher-Beckman Coulter

Stephen H. Wise
Managing Director and Global Head of Healthcare
of The Carlyle Group

QuidelOrtho Senior Management

Douglas C. Bryant
President and Chief Executive Officer

Louise M. Brandy
Senior Vice President and Chief Information Officer

Robert J. Bujarski
Executive Vice President and Chief Operating Officer

Joseph M. Busky
Chief Financial Officer

Michelle A. Hodges
Senior Vice President and General Counsel

Michael S. Iskra
Executive Vice President and Chief Commercial Officer

Patrick E. Klein
Chief Administrative Officer

Werner Kroll, PhD
Senior Vice President, Research and Development

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

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
Computershare, Inc.

Website:	www.computershare.com
Telephone inquiries:	1-800-736-3001, option 1 (U.S.)
	1-781-575-3100, option 1 (non-U.S.)
Email inquiries:	web.queries@computershare.com

Nasdaq Listing
QuidelOrtho common stock is traded on the Nasdaq Global Select Market under the symbol "QDEL."

Form 10-K and Form 10-Q
Copies of QuidelOrtho's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other reports that QuidelOrtho 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
IR@QuidelOrtho.com

QuidelOrtho™

At QuidelOrtho, we transform diagnostic data into answers, understanding and action, illuminating the path forward for all. For more than 80 years, we've pursued the unknown with a passion and purpose to improve health. And we'll continue to transform the power of diagnostics into a healthier future for all.

9975 Summers Ridge Road
San Diego, CA 92121 USA

quidelortho.com