UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31 , 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 CORP ORATION

(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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $ 5,089,571,842 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 22, 2024, 66,849,490 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 2024 Annual Meeting of Stockholders (scheduled to be held on May 14, 2024) 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 DECEMBER 31, 2023

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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, 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"). These statements are any statement contained herein that is not strictly historical, 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, our expected results of operations or financial position, and future plans, objectives, strategies, expectations and intentions. 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. 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 known and unknown 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: supply chain, production, logistics, distribution and labor disruptions and challenges; the challenges and costs of integrating, restructuring and achieving anticipated synergies as a result of the Combinations (as defined in this Annual Report); and other macroeconomic, geopolitical, market, business, competitive and/or regulatory factors affecting our business generally, including those discussed under Part I, Item 1A, "Risk Factors" of this Annual Report. 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. All forward-looking statements are based on information currently available to us and speak only as of the date of this Annual Report. We undertake 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.

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 2023” in this Annual Report refer to the Company’s fiscal year ended December 31, 2023.

Overview

Our vision is to advance diagnostics to power a healthier future. With our expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine, we aim to provide clarity to clinicians and patients to help create better health outcomes. 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 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. For additional information about the Combinations, refer to Part II, Item 8, “Financial Statements and Supplementary Data—Note 2. Business Combination.”

We manage our business geographically to better align with the market dynamics of the specific geographic regions in which we operate, with our reportable segments being 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 Part II, Item 8, “Financial Statements and Supplementary Data—Note 4. Revenue” and “Financial Statements and Supplementary Data—Note 5. Segment and Geographic Information.”

Business Units and Products

We provide diagnostic testing solutions under various brand names, including, among others, the following: AdenoPlus ™, BIOVUE®, FreshCells™, InflammaDry®, Lyra®, MeterPro®, MicroVue™, Ortho®, Ortho Clinical Diagnostics®, Ortho Connect™, Ortho Plus®, Ortho Vision®, QuickVue, Quidel®, QuidelOrtho™, QVue™, 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 intend to enforce our rights to these trademarks, service marks and trade names.

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 performed 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 confirm 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 pairs of tests that are frequently used together onto single slides, 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 Results Management	Advanced informatics software product designed for laboratories of all sizes. It is focused on automating a number of repetitive manual tasks such as sample auto-validation, quality control management, moving averages, STAT sample management, sample archiving, and the development and deployment of advanced rules to help laboratories easily manage their patient populations
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 technology that is easy to run and can process 12 patient samples at the same time
Savanna	CE-marked, 510(k) approved, 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	
Respiratory	Adenovirus, Bordetella Pertussis, 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 Complete
Non-respiratory	Clostridium Difficile (organism), HSV 1+2/VZV, Group Strep B, Trichomonas

POINT OF CARE	
Product	**Primary Application**
Rapid Immunoassay	
Sofia and Sofia 2	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
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, which may reduce hospital admissions and potentially 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, NT-proBNP, 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)
Respiratory Infectious Diseases	Anti-SARS-CoV-2 IgG, Influenza A+B, Influenza A+B & SARS-CoV-2 Ag, RSV, Strep A
Non-respiratory Infectious Diseases	Adenoviral Conjunctivitis, Campylobacter, Chlamydia, Clostridium Difficile (organism), H. pylori Ab, H. pylori Ab (stool), Legionella, Lyme Disease, S. pneumoniae
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

Global Services

In addition to the products we provide, our services are a critical element of how we deliver value to our customers. As of December 31, 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 solutions include:

- 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.
- 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 achieve the highest levels of reliability.
- 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.
- Aquant AI−A field-based machine fed tool used to troubleshoot instrument issues with standardized solutions.

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 building our enterprise digital product strategy, platform and portfolio, which we believe helps improve our customers’ clinical and operational outcomes. Our focus is on enabling our customers to deliver smart, connected care across a variety of clinical environments. We strive to connect our instruments to healthcare providers, labs and policymakers through proprietary and third-party solutions, creating valuable data assets. Our portfolio of workflow automation solutions, such as Ortho Connect, Ortho Plus and myVirena, help simplify the testing and instrument management process. We are also actively developing other products designed to help personalize and elevate individual test results, such as the QVue companion mobile application for our COVID-19 at-home tests, potentially resulting in specific clinical insights or actions.

Our Strategic Capabilities and Competitive Strengths

There is significant competition in the development and marketing of in vitro diagnostic (“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. Some of our principal competitors include, among others, Abbott Laboratories, Roche, Thermo Fisher Scientific, Danaher, Siemens Healthineers, Diasorin, Bio-Rad, Hologic, Qiagen, bioMérieux and Revitty. 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 service program allows us to retain and grow our customer base by providing an industry-leading customer experience driven by quality of service, 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 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 may also enter into strategic partnerships as part of our R&D process.
3. **Operational scale driven by 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 2,900 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 continuous improvement and employee 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.

Business Strategy

We are driven to transform diagnostics into action for more people in more places. We strive to achieve this by serving several market segments throughout the healthcare continuum, from large labs to physicians' offices. While these care settings have historically been distinct and unrelated, healthcare is consolidating. This consolidation translates into community systems consisting of labs, hospitals, physicians' offices and urgent care clinics. Success in one care setting creates new sales opportunities in another care setting within the same system.

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 care 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.

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 $246.8 million for fiscal year 2023, $190.5 million for fiscal year 2022, which includes the impact of Ortho's operations from the date of the Combinations, and $95.7 million for fiscal year 2021. 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 and other respiratory products. 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 field application 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. No customer individually accounted for more than 10% of our Total revenues for fiscal year 2023. See Part II, Item 8, "Financial Statements and Supplementary Data—Note 4. Revenue" for more information.

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 support continuity. Our primary

manufacturing facilities are located in San Diego, California, Carlsbad, California, Athens, Ohio, Raritan, New Jersey, Rochester, New York, Pompano Beach, Florida, and Pencoed, Wales.

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. 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 IVD 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 microwell and equipment manufacturing. The Rochester sites manufacture the slides, microwells 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.

We aim 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 fiscal years 2023 and 2022, we encountered some increasing pressures on raw material pricing, though they were less severe in fiscal year 2023 than in 2022. 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—Supply Chains” 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 December 31, 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

Revenues from our respiratory products are subject to, and significantly affected by, the seasonal demands of the cold, flu and RSV seasons, which are typically more prevalent during the fall and winter. Historically, revenues from our influenza products have varied from year to year based, in large part, on the severity, length and timing of the onset of the cold, flu and RSV seasons. 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 generally Class I or II. Certain of our Vitros immunodiagnostics are Class III.

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. Data and content requirements for premarket submissions, including 510(k) notifications and PMAs, can change over time. For example, beginning in March 2023, premarket submissions for "cyber devices" must contain certain information about device cybersecurity. "Cyber devices" encompass any device that: (1) includes software validated, installed or authorized by the sponsor as a device or in a device; (2) has the ability to connect to the internet; and (3) contains any technological characteristics validated, installed or authorized by the sponsor that could be vulnerable to cybersecurity threats. 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 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. The FDA may also waive otherwise applicable cGMP 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. Some of our current respiratory products were initially authorized by the FDA under EUAs and such EUAs remain in effect until the relevant EUA declaration under Section 564 of the FDCA is terminated or the FDA otherwise revokes a specific EUA. If and when HHS publishes a notice of termination of such EUA declaration, and following the end of any applicable enforcement discretion period, we must comply with applicable FDCA requirements for these respiratory products, including as required, 510(k) notification or PMA submission.

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, 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 include 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 imposes 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 by 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 IVDs. 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. For certain medical devices, the transition period was extended and is scheduled to end between December, 31, 2026 and December 31 2028, depending on the class of the device and the fulfillment of certain additional conditions (EU 2023/607). 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, for certain existing certifications, ranging from May 26, 2025 for high risk IVDs, May 26, 2026 for medium risk IVDs, May 26, 2027 for lower risk IVDs, and to May 26, 2028 for certain provisions concerning devices manufactured and used in health institutions (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 foreign invested enterprises established in China by the licensee of such medical approval license, 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: (1) 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; (2) require that claims for payment submitted to federal healthcare programs be truthful; and (3) require the maintenance of certain government licenses and permits. Specific health-care laws and regulations that we may be 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.

Privacy, Data Security and Data Protection Laws

We are subject to privacy, data security and data protection laws and regulations in numerous jurisdictions, as well as customer-imposed requirements, as a result of having access to and processing confidential, personal and/or sensitive information in the course of our business. Specific privacy, data security and data protection laws that we and our customers may be subject to include:

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which imposes, among other things, privacy, data security and security breach reporting obligations with respect to protected health information ("PHI") on covered entities and business associates. These requirements include entering into agreements that require business associates to protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity and availability of all PHI created, received, maintained or transmitted in electronic form to identify and protect against reasonably anticipated threats to the security and integrity of such PHI or impermissible uses or disclosures of such PHI; and reporting of security breaches involving PHI to individuals, regulators, business associates and the media;
- U.S. state privacy laws that govern the privacy and data security of personal information, including health information, in certain circumstances. The California Consumer Privacy Act of 2018 ("CCPA") creates individual privacy rights for California consumers and imposes privacy and data security obligations on certain entities that do business in California, including to provide specific disclosures in privacy notices and to provide rights to California residents in relation to their personal information. Further, the California Privacy Rights Act ("CPRA"), which amends the CCPA, became fully 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 data protection agency, the California Privacy Protection Agency, which is granted full administrative power, authority, and jurisdiction to implement and enforce the CCPA and CPRA. A similar law in Virginia went into effect on January 1, 2023 and in Colorado and Connecticut on July 1, 2023, and similar laws also have passed in other states, including in Delaware, Indiana, Iowa, Montana, Oregon, Tennessee, Texas and Utah. 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 often relies on Section 5 of the FTC Act to enforce inadequate privacy and data security practices. Section 5 of the FTC Act provides the FTC with broad authority to protect consumers from unfair or deceptive acts or practices in or affecting commerce;
- 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, which govern the processing of personal data in those jurisdictions, and could result in significant fines (up to the greater of €20 million / £17.5 million or 4% of total worldwide annual turnover of the preceding financial year), 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 publishing of revised standard contractual clauses ("SCCs") in 2021, which we must consider and apply, where applicable. When relying on SCCs, the data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures. Where no supplementary measure is suitable, the data exporter shall avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the U.S., on July 10, 2023, the European Commission adopted its adequacy decision for the E.U.-U.S. Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. With regard to the transfer of data from the U.K. to the U.S., the U.K. government has recently adopted an adequacy decision for the U.S., the U.K.-U.S. Data Bridge, which came into effect on October 12, 2023. The U.K.-U.S. Data Bridge recognizes the U.S. as offering an adequate level of data protection where the transfer is to a U.S. company participating in the E.U.-U.S. Data Privacy Framework and the U.K. Extension. 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 geographic 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. While the text of the ePrivacy Regulation is still under development, European court decisions 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;
- Canada's Personal Information Protection and Electronic Documents Act ("PIPEDA"), which governs data protection in the private sector with specific requirements around health privacy and consumer protection. PIPEDA promotes transparency related to personal information collection, requires consent for use, encourages accountability for data handling and imposes obligations on organizations to protect personal data from unauthorized access, breaches and misuse;
- India's Information Technology Act, 2000, which establishes a set of minimum security standards for protection of sensitive personal data, the Reasonable Security Practices and Procedures and Sensitive Personal Data or Information Rules and the newly enacted Digital Personal Data Protection Act, 2023. These directives require that personal data is processed and managed with the utmost care, respecting the rights and dignity of individuals, and promote data security measures to protect against data breaches, cyber-attacks and unauthorized access to personal information;
- 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.

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. These laws generally prohibit us and our intermediaries from, among other things, 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.

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, when applicable to our products and services, 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 existing patents, 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 or other compensation (some of which may be significant) in order to pursue certain of our future product strategies. Moreover, licenses to such patents may not be available to us at all or may not be available on acceptable terms.

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 attributable to our products sold under those agreements.

Human Capital and ESG Strategies

Human Capital Resources

As of December 31, 2023, we had approximately 7,100 employees worldwide, with approximately 4,200 employees in the U.S. and approximately 2,900 employees outside of the U.S. We employ approximately 1,800 manufacturing employees and approximately 2,900 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 employees to participate in a confidential, global survey to gather feedback and gain insights on key cultural and engagement factors and approximately 75% of our global employees participated in the survey. In June 2023, approximately 85% of our global employees participated in a subsequent, follow-up pulse survey. Respondents of both the 2022 and 2023 surveys indicated a strong alignment to our strategic priorities and find meaning and purpose in their work. We believe we are stronger together and intend to prioritize actions that support happy, inspired and engaged team members. We plan to conduct periodic pulse surveys with employees throughout 2024 to measure progress and focus on further improvements.

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 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 December 31, 2023, 42% of our U.S. employees identified as female and 37% of our U.S. employees identified as having a racial and ethnic background other than white. As of December 31, 2023, our executive management team consisted of 8 members, of whom 25% identified as female. In addition, as of December 31, 2023, our board of directors (the "Board") consisted of 11 members, of whom 27% self-identified as female and 18% self-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, when applicable. 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, family forming 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 rewards and 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 Gift. Impact. Volunteer. Empower. (G.I.V.E.) program. Our charitable giving programs and activities in the U.S. consist of the following:

- Matching gifts−We match charitable contributions made by active employees to qualifying non-profit organizations of up to $200 per employee annually.
- Volunteer incentive program−When an employee volunteers at a qualifying organization for a minimum of 20 hours in a calendar year, we donate $100 to that organization.
- General grant fund−We may donate up to $2,000 to a qualifying 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.
- Community initiatives and philanthropic programs−We contribute to a variety of community initiatives and philanthropic programs, including research partnerships, blood drive sponsorships, COVID-19 testing drives, medical supply donations, scholarship and internship programs, as well as STEM programs with educational institutions.

ESG Strategy

We are driven by a purpose to improve the quality of life for people all over the world by enabling more informed health decisions when and where they need them most. We champion an authentic culture of service, empowering every employee to do their best. We strive to create innovative products that are efficient, trusted, accessible and sustainable to support better outcomes for patients and practitioners.

Our goal is to align our corporate actions in the areas of environmental sustainability, social responsibility, ethics, diversity and inclusion, corporate governance and supply chain ecosystem responsibility to have a positive impact on our communities and for all our stakeholders in ways that provide value to our stockholders.

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:

- 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 respiratory products;
- 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;
- 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, divestitures or discontinuances of certain business 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;
- failure to integrate successfully the businesses of Quidel and Ortho in the expected timeframe;
- continued incurrence of significant transaction and merger-related costs;
- our inability to protect our information systems and personal and confidential information from data corruption, cyber-attacks and security breaches;
- interruptions to our third-party IT service providers and/or the inability of our digital solutions to interoperate with certain operating systems;
- 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 EUAs on our respiratory 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 them from performing normal business functions or prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner, or at all;
- 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 privacy, data security and data protection laws and regulations;
- risks related to changes in U.S. and foreign income tax laws and regulations;

- need to raise additional funds to finance our future capital or operating needs or other business purposes;
- risks related to our indebtedness;
- 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 defined benefit plans or other post-employment benefit 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;
- additional costs and new risks associated with ESG matters, including evolving legal standards and regulations concerning such matters;
- 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"), our amended and restated bylaws (our "Bylaws") and Delaware law 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;
- 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 Our Business, Strategy 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, products and services, 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 and services 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 more established, larger and broader coverage in 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 and services 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. 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, or at all, 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.

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, a recessionary environment, instability in financial institutions and budgeting constraints of governmental entities. Disruptions in the U.S., Europe, China or in other geographies, including as a result of the ongoing conflict in Ukraine and the Israel-Hamas conflict, or weakening of emerging markets, such as China, could adversely affect our sales, profitability and/or liquidity.

A deterioration in financial markets, including due to instability in financial institutions, or reduction in 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 respiratory products could materially and adversely affect our operating results.

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 respiratory products have represented a significant portion of our total revenues. Sales of our respiratory products accounted for approximately 24% of our total revenues for the year ended December 31, 2023. Demand for

our respiratory products has and may continue to fluctuate or decline as a result of a number of factors, including but not limited to the severity of the respiratory season, the emergence and impact of new variants or resurgences, the effectiveness of vaccination efforts, and the increased market supply of respiratory products by our competitors. The gross margins derived from sales of our respiratory products are generally significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our respiratory products fluctuate or decline for any reason, whether as a result of COVID-19 reaching an endemic stage, a mild respiratory season, market share loss or price pressure, obsolescence, regulatory matters, 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 or in direct sales. 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 direct customers who are significant. If our relationships with these 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.

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 or to direct sales, 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 terms of our arrangements with any of them could adversely affect our financial condition and results of operations. In addition, 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. We cannot predict the frequency, duration or scope of these supply, production, logistics, distribution and labor disruptions and challenges.

Unexpected increases in demand for our products or services or supply shortages could require us to incur additional costs to meet customer demand. These costs could involve purchasing or producing a safety stock of components or products, purchasing new machinery, obtaining additional labor resources or even acquiring or constructing new manufacturing facilities. 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 shortage, or the cost of such supplies may be significantly greater. This would increase our capital and other costs, which could adversely affect our earnings and cash resources. Additionally, our reliance on a small number of contract manufacturers and a large number of single and sole source suppliers makes us vulnerable to possible production capacity or other constraints of such suppliers or in their supply chain and reduced control over manufacturing, product availability, delivery schedules and costs.

While 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, such disruptions and challenges have materially affected and could further materially affect our ability to timely manufacture and distribute our products and have unfavorably impacted and could further unfavorably impact our results of operations. As a result, we have encountered, and may in the future encounter, significant customer backlogs of orders and inventory shipments. Further significant customer backlogs and

our inability to meet customer demand for our products and services may adversely impact customer relationships, impair our reputation 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. 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 or other actions by the FDA and other regulatory authorities that could hinder their ability to produce necessary raw materials, products and components. The implementation of these requirements has caused and will continue to cause increased costs to comply with these 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 or continue existing terms under supply arrangements, 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 shortage 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, natural disasters, public health crises 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 supply 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 contract manufacturers, with no or limited alternate facilities. 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, Pompano Beach, Florida, and Athens, Ohio. Severe weather, natural disasters, public health crises, fires, power shortages or outages, 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, catastrophic events or other events outside of our control, 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, suppliers or other third-party vendors on which we depend, could delay, reduce, suspend or terminate production of products or the release of new products, result in the delivery of inferior products or otherwise disrupt our operations. In such circumstances, our revenue 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, suppliers or third-party vendors. 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. 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.

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 can result in decreased demand for blood for transfusions, resulting in lower testing volumes and, therefore, decreased sales of our products. In addition, blood is a large expense for hospitals and pressure on hospital budgets due to macroeconomic factors and healthcare reform could force changes in the ways in which blood is used and lower blood demand. 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 by 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 and services, including our new products. If we do not capture sales at the levels anticipated, 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 and services compared to alternative products. 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 lower acceptance or fewer 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, and these payors may reduce or modify reimbursement rates. For example, 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. Such 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.

Such changes 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, the formation of group purchasing organizations and government-sponsored tendering processes 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. For example, the Chinese government has started to expand its volume-based procurement (“VBP”) program to diagnostics at the provincial level, which aims to lower prices in exchange for high volume purchases. Some of our immunoassay products fall within the VBP scope in Anhui Province in China. 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 or divestitures or discontinue business operations, and may encounter difficulties integrating acquired businesses with, or disposing of divested or discontinued businesses from, our current operations; therefore, we may not realize the anticipated benefits of these acquisitions, divestitures or discontinuances.

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 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 or discontinue certain business operations from time to time if certain of our businesses do not meet our strategic, growth or profitability objectives. For example, in February 2024, we initiated a wind-down plan to transition out of the U.S donor screening portfolio, which has a lower growth and margin profile than other parts of our Transfusion Medicine business. 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. There can be no assurance that we will be able to complete any such divestiture on terms favorable to us. The divestiture or discontinuance of certain businesses could result, individually or in the aggregate, in the recognition of material losses and a material adverse effect on our results of operations.

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 adversely impact our financial performance, cause interruptions in our business operations, impede our international growth and subject us to civil or criminal penalties, other remedial measures and legal expenses. 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;
- 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, customer 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 sanction regimes, including future regulations and sanctions that could further limit the countries in which our products may be manufactured or sold, increase the cost of conducting business in these countries, or restrict our access to, or increase the cost of obtaining, products from foreign sources;
- 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 where we may expand into in the future, including as a result of conflicts, including the ongoing conflict in Ukraine and the Israel-Hamas conflict, acts of terrorism, civil unrest, wars, pandemics, endemics or other public health crises, environmental incidents and disruptions in global transportation;
- increased financial accounting and reporting burdens and complexities;
- import and export duties, changes to import and export regulations, customs regulations and processes, and restrictions on the transfer of funds, including currency controls;
- complex and potentially adverse tax consequences resulting from international tax laws;
- transportation difficulties and delays resulting from inadequate local infrastructure; and
- diversion of our products into the U.S. or other markets that are sold into other 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.

Risks Relating to the Consummation of the Combinations and our Transformation Efforts

The failure to integrate successfully the businesses of Quidel and Ortho would adversely affect our future business and financial performance.

As a result of the Combinations, we have been and continue to devote significant management and employee attention and resources to integrate the business practices and operations of Quidel and Ortho. The integration process may disrupt our business and, if implemented ineffectively, could preclude realization of the full 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 integration of Quidel and Ortho may result in material unanticipated problems, expenses and liabilities. The difficulties of combining the operations of Quidel and Ortho, some of which we have already experienced, include, among others:

- managing a significantly larger company and expanded business operations and the associated increased costs and complexity;
- aligning and executing our strategy;
- inconsistencies in standards, controls, systems, procedures and policies;
- the possibility of faulty assumptions underlying expectations regarding the integration process and results;
- coordinating sales, distribution and marketing efforts;
- integrating IT, enterprise resource planning (“ERP”), customer relationship management and other systems, including the implementation of a new ERP system to integrate certain existing business, operational and financial processes, which requires significant investment of capital and human resources and the reengineering of many business processes;
- managing tax costs or inefficiencies associated with integrating the operations of Quidel and Ortho; 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 subject us to increased costs, decreased revenues and diversion of management’s and employees’ time and energy, which could materially impact our business, financial condition and results of operations. In addition, we are transitioning from integration efforts of the two independent businesses to focusing on transformation of the combined company with the goal of creating a more efficient and agile company. We may not realize the full benefits of the Combinations, including the synergies, cost savings or sales or growth opportunities that we expect from the Combinations and transformation, or these benefits may take longer to realize than expected. If we are unable to realize the anticipated benefits and synergies expected from the Combinations and transformation within the anticipated timeframe, 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. There are processes, policies, procedures, operations, technologies and systems that still 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. 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.

Risks Relating to Our IT Systems

Our ability to protect our information systems and personal and confidential information from data corruption, cyber-attacks and security breaches 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 provide our products and services, including operating our instruments and devices, and those networks and systems managed by vendors or third parties, to securely collect, process, transmit, disclose, share, use and store electronic information (including sensitive personal information and proprietary or confidential information) (collectively, "information systems"). Our information 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 personal or confidential information, all of which can be timely and costly to remediate. In addition, a security breach that impacts personal information could require us to comply with breach notification requirements under applicable data privacy and security laws, result in litigation or regulatory action, or otherwise subject us to liability under those laws.

If we experience a significant incident, such as a serious product vulnerability or security breach, or any other disruptions, delays or deficiencies from our ERP systems, it could adversely affect our ability to, among other processes, 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 our information systems, data and infrastructure. An actual or perceived vulnerability, failure, disruption or breach of our information 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 from insurance premiums and remediation measures and subject us to potential liability, litigation and regulatory or other government action. If any of the foregoing were to occur, our business strategy, results of operations or financial condition could be materially and adversely affected.

We attempt to mitigate the above risks by employing a number of measures, including implementing technical, physical and organizational security measures, monitoring and testing our security controls, conducting employee training and maintaining protective systems and contingency plans. Further, our contractual arrangements with service providers aim to appropriately mitigate third-party cybersecurity risks. We also maintain insurance coverage for cybersecurity incidents, which may not be adequate or cover all incidents. It is impossible to eliminate all cybersecurity risk and thus our information systems, products and services, as well as those of our service providers, remain potentially vulnerable to known or unknown threats. Additionally, our information systems may be vulnerable to damage or interruption from circumstances beyond our control, including fire, natural disasters, power outages and system failures.

Cybersecurity 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 increased number of our employees with flexible work arrangements, we may also face increased cybersecurity risks due to our reliance on internet technology, which may create additional opportunities and vulnerabilities for cybercriminals to exploit. 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 cybersecurity risks 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 and investigate and remediate security vulnerabilities.

For more information on our cybersecurity risk management, strategy and governance, see Part I, Item 1C, "Cybersecurity."

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 severe 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 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, trade secrets, know-how and trademarks in the U.S. and certain other countries. We make strategic decisions on whether to apply for intellectual property protection and the types 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 know-how and unregistered rights in and to our products and it is possible that others will independently develop the same trade secrets, know-how and unregistered rights or obtain access to our trade secrets, know-how and unregistered rights. We license some of the rights to use our patents, trade secrets 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, including upon termination of our licenses or collaboration agreements, or failure to police our intellectual property, including through our licensees, could have a material adverse effect on our business, results of operations and financial condition.

Intellectual property risks, third-party claims of infringement, misappropriation or violation of proprietary rights and 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 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 technical or scientific information 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 matters. Moreover, an adverse determination in any of these types of disputes could prevent us from developing, using, manufacturing or selling some of our processes or products and services; 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 Regulation

Regulation of Our Industry and Products

Some of our respiratory products were authorized by the FDA through an EUA and the loss of such authorization could have a material adverse effect 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 EUA-approved 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 cGMP requirements to accommodate emergency response needs. Some of our current respiratory products were initially authorized by the FDA under EUAs.

HHS intends to publish advance notice of termination of each EUA declaration pertaining to medical devices in the Federal Register 180 days before the day on which the EUA declaration is terminated. HHS has not yet published such notice of termination for the EUAs we hold. While we have been working closely with the FDA to obtain traditional premarket clearance for some of our respiratory products by submitting de novo and 510(k) submissions, the loss of one or more of our EUAs for our respiratory products, if we are unable to timely obtain traditional premarket clearance, 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. 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.

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. We 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 our 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 or approval, and we may be subject to civil, criminal, monetary and non-monetary penalties and damage to our reputation.

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.

In addition, the advertising, marketing and labeling of medical devices are 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 obtain regulatory approval and 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 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.

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, including disruptions caused by funding shortages or statutory, regulatory or policy changes, could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent them from performing normal business functions on which the operation of our business may rely, 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, such as those 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. For example, over the last several years the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, or to provide feedback on our submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other disruptions to normal operations could impact our ability to access the public markets and obtain funding necessary to properly capitalize and continue our operations.

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, challenges from other industry participants, 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 or other vendors 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 time-consuming. 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 may 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 subject 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 seizures, 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 support compliance of our third-party business arrangements 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. Department of Health and Human Services 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, corporate integrity agreement or other type of government resolution. 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, state or foreign 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, corporate integrity agreement or other government resolution, 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.

Certain Other Regulations Relating to Our Business

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 FCPA also contains accounting provisions requiring issuers of securities listed in the U.S. to make and keep books and records that accurately and fairly reflect the transactions and dispositions of the assets of the company, and to devise and maintain an adequate system of internal accounting controls. 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 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, and confidential information is subject to federal and state privacy, data security and data protection regulations, as well as privacy, data security and data protection 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 this information could result in significant liability or reputational harm.

In the ordinary course of business, we collect, process, transfer, disclose, share and use personal and confidential information, including from customers, employees and business contacts. These activities may subject us and our partners to federal, state and foreign privacy, data security and data protection laws, regulations, guidance, self-governing rules, industry standards, contractual requirements and other obligations as further described in Part I, Item 1, "Business—Government Regulations" of this Annual Report.

In the U.S., there are various laws regulating data privacy and security at the federal, state and local level, some of which are further described in the "Business—Government Regulations" section of this Annual Report. We are also subject to other regulations, guidance, self-governing rules, industry standards and contractual requirements. The legislative and regulatory landscape for privacy, data security and data protection continues to evolve, with jurisdictions in which we and our customers operate adopting or considering adopting new privacy, data security and data protection laws and regulations regarding the collection, use, processing, transfer, disclosure, sharing, security and storage of information obtained from consumers, employees and other individuals, including health-related information. There is also an increasing focus on incident response and breach notification requirements with regulations dictating how to prepare for, respond to and report security incidents and breaches. We may also be bound by contractual obligations with our customers relating to privacy, data protection and data security that are more stringent than applicable privacy, data security and data protection 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 that does not align with our business objectives (including limiting our ability to collect, control, process, share, disclose and otherwise use personal information (including health and medical information that 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 inquiries by U.S., federal, state and foreign data protection regulatory agencies, all of which could result in sanctions, investigations, fines, penalties or otherwise 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 recent, 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 data security concerns, even if unfounded, could result in significant cost and liability to us, including civil and/or criminal penalties, injunctions, fines and exposures to private litigation, as a cost of doing business, or due to new or increasing fines or penalties for violations, damage our reputation, and adversely affect our business and results of operations. Further, a cyber-attack or other security breach affecting personal information, including health or employee information, could also result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business, including limiting our ability to process personal information or to operate in certain jurisdictions.

We continue to monitor the evolving privacy, data security and 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.

We are subject to income taxes in the U.S. and in various non-U.S. jurisdictions. 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 significant changes could adversely affect our financial statements.

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 and complexity 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. Additionally, 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. 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. We continue to monitor changes in tax laws and the impact of proposed and enacted legislation in the U.S. and in the various foreign jurisdictions in which we operate.

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 consist of (i) a Term Loan in an original amount of $2,750.0 million and (ii) an $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 December 31, 2023, we had total indebtedness of $2,414.6 million, and we had availability under our Revolving Credit Facility of $787.1 million (net of $12.9 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 hedging instruments or any future hedging instruments we enter into may not fully or effectively mitigate our interest rate risk and we may decide not to maintain hedging instruments 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 may 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 when 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 Part II, Item 8, "Financial Statements and Supplementary Data—Note 8. Borrowings" for more information related to our financial covenants.

Our ability to comply with these covenants may be affected by financial, business, economic, regulatory and other circumstances and events beyond our control, such as prevailing economic conditions, changes in regulations and industry conditions, and we cannot assure you that we will be able to comply with such covenants. For example, compliance with the financial covenants would be more difficult to achieve if we were to experience substantially lower revenues or greater costs than budgeted. The covenants under the Credit Agreement 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, or if we are unable to comply with any of the covenants, we may need to seek an amendment or waiver from our lenders of various provisions in the Credit Agreement and we may not be able to obtain such an amendment or waiver on reasonable terms, if at all. Additionally, our costs under these agreements would likely increase. A breach of any of the covenants under our Credit Agreement could result in an event of default, which could result in the accelerated payment of outstanding indebtedness or foreclosure on our assets pledged to secure the indebtedness, which could have a material adverse effect on us.

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, motivate and retain 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. Accordingly, no assurance can be given that we will be able to attract or retain executives or key employees. 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. In addition, there could be disruptions to or distractions for the workforce and management, including in connection with activities of labor unions or work councils. While we may employ the use of certain retention programs, there can be no guarantee that they will prove to be successful. 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.

If we are required to make unexpected payments to any defined benefit plans or other post-employment benefit plans ("Benefit Plans") applicable to our employees, our financial condition may be adversely affected.

Some of our current and former employees participate or participated in Benefit Plans that were sponsored by Ortho prior to the closing of the Combinations. We assumed certain underfunded and unfunded Benefit Plan liabilities, which amounted to approximately $36.0 million as of December 31, 2023. Several of these plans are unfunded and, while we do not believe the

liabilities in relation to these plans are significant, they must be satisfied as they mature from our cash resources. In jurisdictions where the Benefit 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 Benefit 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 Benefit Plans.

We could also be required in some jurisdictions to make accelerated payments up to the full buy-out deficit in our Benefit 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 Benefit Plans in excess of the amounts assumed in our current projections and assumptions or (ii) report higher Benefit 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 December 31, 2023, we had approximately 7,100 employees located around the world consisting of commercial, supply chain, quality, regulatory and compliance, R&D and general administrative personnel. As of such date, approximately 15% of our employees globally were 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 subject 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 FDA may also withdraw any clearances or approvals we have obtained, or decline to issue additional clearances or approvals for any outstanding 510(k)s, PMAs or BLAs. 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.

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 the SEC and other regulators, investors, customers, suppliers, vendors, employees and other stakeholders concerning corporate responsibility and sustainability and ESG factors in particular. Government entities are enhancing or advancing legal and regulatory requirements, including disclosure requirements, specific to ESG matters. For example, the state of California has adopted new climate change disclosure requirements and the E.U. has adopted the Corporate Sustainability Reporting Directive. Compliance with such rules could require significant effort and resources and result in changes to our current ESG goals. Additionally, many investors use ESG factors to help guide their

investment strategies and, in some cases, may choose not to invest in us if they believe our ESG performance is inadequate. Moreover, a number of customers who are payors or distributors have adopted, or may adopt, procurement policies that include ESG provisions that their suppliers or manufacturers must comply with, or they may seek to include such provisions in their terms and conditions.

Standards for tracking and reporting ESG matters continue to evolve. Our use of disclosure frameworks and standards, and the interpretation or application of those frameworks and standards, may change from time to time or differ from those of others. This may result in a lack of consistent or meaningful comparative data from period to period or between us and other companies in the same industry. Third-party providers of corporate responsibility ratings and reports have also increased in number to meet growing stakeholder demand for measurement of ESG performance. The criteria by which our corporate responsibility practices are assessed must be routinely 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 evolving standards for identifying, measuring and reporting ESG metrics, including ESG-related disclosures that may be required of public companies by the SEC and other regulators, stakeholders 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 or our standards for measuring and reporting such goals. Our failure to satisfy stakeholder expectations related to our ESG performance or to accomplish or accurately track and report on our ESG goals on a timely basis, or at all, could result in the loss of business or difficulty obtaining new business or new supplier relationships, adversely affect our reputation, stock price, financial condition, results of operation or growth, expose us to increased scrutiny from stakeholders and enforcement authorities, which may result in litigation or regulatory action or otherwise subject us to liability, and present challenges in attracting and retaining talented employees.

We are exposed to business risk which, if not fully 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 risks. 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 payments or other 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. 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.

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;
- additions or departures of key personnel; and
- issuances, repurchases or sales of our common stock, including sales of common stock by our directors and officers or our significant investors and any stock repurchase program.

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 December 31, 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 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 1C. Cybersecurity

We are committed to maintaining effective governance and oversight of cybersecurity risks. Our cybersecurity strategy focuses on implementing effective and efficient mechanisms, controls, technologies, systems and other processes across our global IT networks and systems to assess, identify and manage material risks from potential unauthorized occurrences on or through our IT systems that may result in adverse effects on the confidentiality, integrity or availability of our IT systems and the data residing therein. These processes are designed to promote (i) strong controls across our entire IT ecosystem, (ii) transparency across our IT infrastructure so that our information security team can detect, identify and escalate anomalies for further analysis and action, and (iii) a sound enterprise security architecture with security integrated into each phase of system implementation. We believe that the processes and controls we have established to protect our stakeholders' interests, including with respect to our current regulated products and internal systems, are robust and aligned with applicable cybersecurity regulations and certain identified industry best practices. This includes security by design, regular penetration testing, vulnerability scanning and standardization where possible of cybersecurity architecture principles.

Our cybersecurity risk management is part of our broader enterprise risk management process, which is managed by our internal audit team with oversight from our executive leadership, and ultimately, the Audit Committee and the Board. Supported by a global team of information security professionals, we have in place a variety of tools, processes and services designed to identify the impacts of changing cybersecurity threats within our IT networks and systems and those networks and systems managed by key vendors or third parties. Cybersecurity risks are identified, quantified and mitigated by leveraging detection and preventive technologies, including security monitoring, intrusion detection and prevention systems, routine risk assessments, a vulnerability management infrastructure and a global incident response program. In addition, we also periodically consult with outside advisors and experts to anticipate future trends, such as threats and issues within the healthcare industry as well as updates on key regulatory changes, including evolving cybersecurity policies and mandates from the FDA and the Cybersecurity and Infrastructure Security Agency.

We identify and address cybersecurity risks associated with key third-party service providers through security and privacy assessments prior to engaging these third parties, the breadth of which is determined by factors such as the type of data, if any, the third party will have access to, whether the third party will have access to our networks and systems, and whether the third party will provide hardware or software to be used in our products or elsewhere in our organization. Depending on the results of these assessments, we may conduct further assessments prior to or periodically throughout the course of our engagement limit or cease plans to engage the third party, or negotiate specific contractual protections or remediation provisions.

We also aim to improve our identity and access management by limiting individuals' access to information only to that which is necessary to conduct their official duties and granting individuals access privileges only to user accounts or processes that are essential to perform their intended functions. Multi-factor authentication and role-based access controls are also core elements of our identity and access management processes. Additionally, we periodically offer training and education to our employees on cyber risks and remind our employees of critical end-user best practices, such as current phishing trends. Information security risk is managed by a cross-functional team, which includes our procurement, compliance, privacy and legal teams, allowing for a holistic view of risks related to the safety and privacy of critical data, such as customer account details, financial

data and intellectual property. We aim to secure our data and information throughout their lifecycle – from creation, collection and processing to dissemination, use, storage and disposition.

While we have not identified any material cybersecurity threats or incidents during the last fiscal year, there can be no guarantee that we will not be the subject of future successful attacks, threats or incidents. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, “Risk Factors,” under the heading “Risks Relating to Our IT Systems.”

Oversight of cybersecurity risk involves a three-tiered hierarchy designed to leverage the appropriate level of expertise to assess and manage such risks. This consists of our Chief Information Security Officer (“CISO”), Security Governance Committee (“SGC”) and the Audit Committee of the Board. Our CISO is primarily responsible for our global information security program. In this role, the CISO is responsible for the effective operations of information security controls and management of information security and cybersecurity risks across the enterprise, including within our products and operations. The CISO also aligns our information security strategy with our business and technical strategies and integrates, where possible, security initiatives into roadmaps of other functions to promote accountability and awareness. The CISO is also responsible for developing and implementing our information security policies and standards in accordance with applicable global regulatory requirements and facilitating updates to these policies and standards at least annually. Our CISO has 20 years of global information security leadership experience across financial services, legal and medical device industries and over 35 years of broader IT experience.

The SGC is comprised of members of our executive leadership team, including the Chief Financial Officer, Chief Operating Officer, General Counsel, Chief Administrative Officer, Chief Information Officer (“CIO”) and CISO. The CISO reports to the SGC on a regular basis, and informs the committee of critical risks that could potentially affect our information security and cybersecurity posture, as well as regulatory compliance; the status of key projects designed to evolve our information security programs; and any significant cybersecurity issues, incidents and patterns of events. The SGC has the authority to (i) investigate any matter brought to its attention that may impact our ability to adequately protect our information assets and (ii) to involve its members, the Board, other steering committees, government agencies and law enforcement, as it deems appropriate to respond to and remediate such matters. The CISO provides updates to the SGC during the course of significant cybersecurity incidents and in parallel, response teams partner with our IT and legal teams, law enforcement and others as needed to triage and remediate such incidents. Following such events, we implement changes as appropriate to improve our risk mitigation and remediation capabilities as cyber threats evolve.

The Audit Committee of the Board oversees our cybersecurity risk management and strategy and has an oversight role that involves reviewing, establishing policies for, and assessing the efficacy of processes used to evaluate significant risk exposures and the measures management implements to mitigate these risks. The Audit Committee is informed about cybersecurity risks through regular management reports on the performance of internal and/or external cybersecurity audits and assessments and the effectiveness of existing cybersecurity practices. The CIO, CISO, other members of the SGC, and other personnel also periodically update the Audit Committee on material cybersecurity risks, significant cybersecurity incidents, mitigation measures and impacts to the Company. The Board receives updates from management, including the CIO, and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. Properties

At December 31, 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	149,240	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
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 Part II, Item 8, “Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies—Litigation and Other Legal Proceedings” 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 22, 2024, we had approximately 88 common stockholders of record and we do not anticipate paying any cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

The table below sets forth information regarding repurchases of our common stock by us during the three months ended December 31, 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 2, 2023 - October 29, 2023	3,674	$ 66.64	—	$ 225,677,460
October 30, 2023 - November 26, 2023	121,783	60.28	120,000	218,444,460
November 27, 2023 - December 31, 2023	858	70.68	—	218,444,460
Total	126,315	$ 60.54	120,000	$ 218,444,460

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

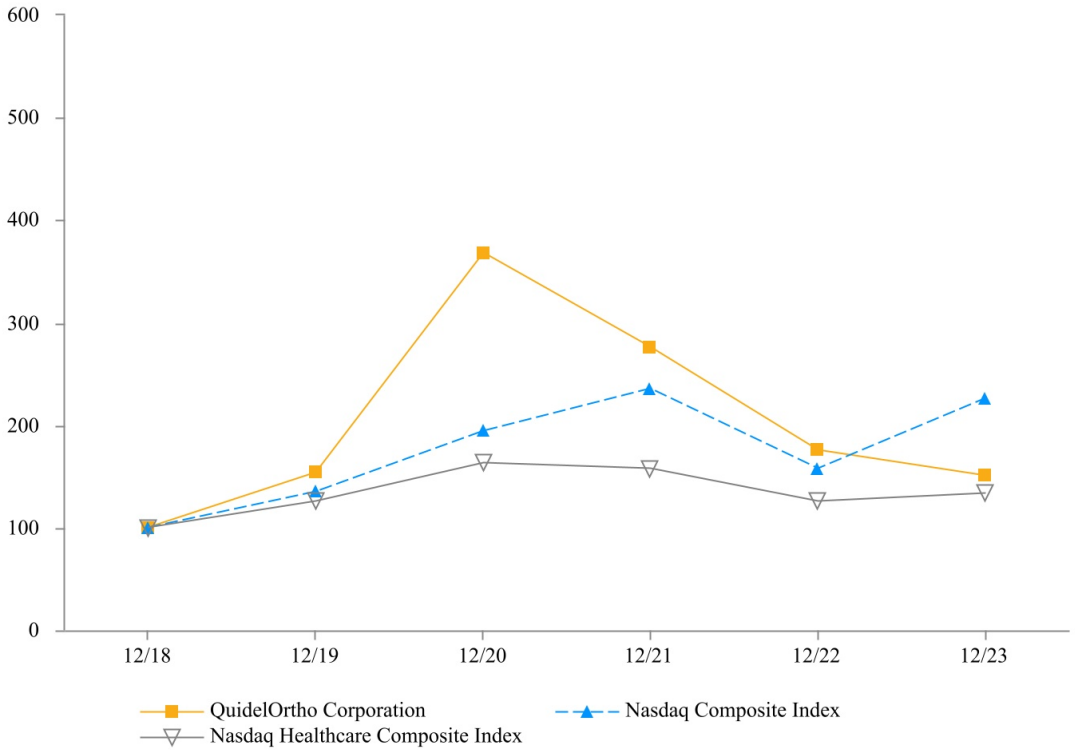
(2) On August 17, 2022, the Board authorized a stock repurchase program, allowing the Company to repurchase up to $300.0 million of its common stock through August 17, 2024 (the "Stock Repurchase Program"). During the three months ended December 31, 2023, the Company repurchased 120,000 shares of outstanding common stock under the Stock Repurchase Program for approximately $7.2 million.

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 Composite Index for the five years ended December 31, 2023. The graph assumes (i) an initial investment of $100 as of the market close on December 31, 2018 in our common stock, the Nasdaq Composite Index and the Nasdaq Health Care Composite Index and (ii) reinvestment of dividends. The graph represents stock price performance of Quidel, from fiscal year 2019 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.

COMPARISON OF 5 YEAR TOTAL CUMULATIVE RETURN

Among QuidelOrtho Corporation, the Nasdaq Composite and the Nasdaq Health Care Composite Indices



	Base Period					
Company/Index	**12/31/2018**	**12/31/2019**	**12/31/2020**	**12/31/2021**	**12/31/2022**	**12/31/2023**
QuidelOrtho Corporation	**$ 100.00**	$ 153.69	$ 367.98	$ 276.51	$ 175.48	$ 150.96
Nasdaq Composite Index	**$ 100.00**	$ 135.23	$ 194.24	$ 235.78	$ 157.74	$ 226.24
Nasdaq Health Care Composite Index	**$ 100.00**	$ 125.83	$ 163.63	$ 157.82	$ 125.58	$ 133.80

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 operation

s 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 vision is to advance diagnostics to power a healthier future. With our expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine, we aim to provide clarity to clinicians and patients to help create better health outcomes. 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 manage our business geographically to better align with the market dynamics of the specific geographic regions in which we operate, with our reportable segments being 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.

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. Our Consolidated Financial Statements for 2023 include a full year of Ortho operations. For additional information about the Combinations, see Part II, Item 8, "Financial Statements and Supplementary Data—Note 2. Business Combination."

For fiscal year 2023, Total revenues decreased by 8% to $2,997.8 million as compared to the prior year. 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 100 basis points and 300 basis points on our growth rate for fiscal years 2023 and 2022, respectively. Our revenues can be highly concentrated over a small number of products, including certain of our respiratory products. For fiscal years 2023, 2022 and 2021, revenues related to our respiratory products accounted for approximately 24%, 57% and 81% of our Total revenues, respectively, primarily driven by sales of our COVID-19 products.

Planned Wind-Down of U.S. Donor Screening Portfolio

In February 2024, we initiated a wind-down plan to transition out of the U.S. donor screening portfolio. Specifically, we plan to wind-down only the VIP platform and microplate assays, which are only sold in the U.S., and have a lower growth and margin profile than other parts of our Transfusion Medicine business. This wind-down will not affect any donor screening portfolio outside of the U.S. While our goal is to wind-down this U.S. donor screening portfolio, we will continue to support our existing customers and honor our contractual commitments.

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. While we have made notable improvements in 2023, these supply, production, logistics, distribution and labor disruptions and challenges have impacted, and we expect will continue for some period of time to impact, our operations. However, the significance and frequency of such impact have lessened during the fourth quarter of 2023.

Some of our raw materials are available from a limited number of sources. During 2023 and 2022, we encountered some increasing pressures on raw material pricing, though they were less severe in fiscal year 2023 than in 2022. To mitigate these supply chain challenges, we continue to (i) partner with suppliers to invest in additional capacity and raw material inventory, (ii) diversify our supply base, where possible, to minimize reliance on a single source of supply for key raw materials and components and (iii) create 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 have been investing in and implementing automation capabilities to help improve accuracy and timeliness of customer shipments.

We continue to monitor these macroeconomic and geopolitical developments 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 materially affected and could further materially affect our ability to timely manufacture and distribute our products and could unfavorably impact our results of operations depending on the nature and duration of such disruptions and 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, duration and emergence of new variants of respiratory diseases, including flu, strep, RSV and COVID-19, as well as ongoing supply, production and logistics challenges.

Demand for our respiratory products, which includes our COVID-19 products, declined in 2023 compared to 2022 due to the end of the U.S. public health emergency regarding COVID-19 and the transition of COVID-19 from a pandemic to an endemic environment. We expect demand for our respiratory products to continue to fluctuate and pricing pressures on certain products to persist as a result of a number of factors, including increased supply, emergence and spread of new variants, and the seasonal demands of the respiratory seasons, which are typically more prevalent during the fall and winter.

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 efficiencies. 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 we expect the revenues and financial results from our respiratory products to be affected by the seasonal demands of the respiratory seasons, 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 2023, 2022 and 2021

Our fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. Fiscal years 2023, 2022 and 2021 were 52 weeks.

Revenues

The following table compares Total revenues by business unit for fiscal years 2023, 2022 and 2021:

	Fiscal Year Ended				
(Dollars in millions)	2023	2022	2021	% Change 2023 vs. 2022	% Change 2022 vs. 2021
Labs	$ 1,425.4	$ 820.2	$ 44.8	74 %	1,731 %
Transfusion Medicine	648.5	393.8	—	65 %	N/M
Point of Care	892.2	1,955.3	1,453.3	(54)%	35 %
Molecular Diagnostics	31.7	96.7	200.5	(67)%	(52)%
Total revenues	$ 2,997.8	$ 3,266.0	$ 1,698.6	(8)%	92 %

* N/M - Not meaningful

For fiscal year 2023, Total revenues decreased to $2,997.8 million from $3,266.0 million for the prior year. The increases in Labs and Transfusion Medicine revenues were primarily related to incremental revenues from the Combinations. Additionally, the increase in Labs revenue included a $19.2 million settlement award from a third party related to one of our collaboration agreements. The Point of Care business unit contributed to revenue decline, driven by decreases of $846.0 million in sales of QuickVue SARS Antigen assays and $219.1 million in sales of Sofia SARS Antigen assays. Molecular Diagnostics revenue decreased by $65.0 million, primarily driven by lower demand for the Lyra SARS Antigen assay due to the end of the public health emergency in the U.S. Currency exchange rates had an unfavorable impact of approximately 100 basis points on the growth rate for fiscal year 2023.

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, primarily driven 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 revenue decreased by $103.8 million, primarily driven by lower demand and pricing of the Lyra SARS Antigen assay. Currency exchange rates had an unfavorable impact of approximately 300 basis points on the growth rate for fiscal year 2022.

Cost of Sales, Excluding Amortization of Intangible Assets

Cost of sales, excluding amortization of intangible assets, increased to $1,503.4 million, or 50.2% of Total revenues, for fiscal year 2023, compared to $1,330.0 million, or 40.7% of Total revenues, for fiscal year 2022. The increase in cost of sales, excluding amortization of intangible assets as a percentage of revenue, was primarily driven by incremental revenues in the Labs and Transfusion Medicine business units as a result of the Combinations and a decrease in sales of respiratory products. We also recorded $60.6 million of expense related to the unwind of the inventory fair value adjustment related to the Combinations during fiscal year 2022.

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 primarily driven 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 unwind 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.

Operating Expenses

The following table summarizes operating expenses for fiscal years 2023, 2022 and 2021:

	Fiscal Year Ended					
(Dollars in millions)	2023	% of Total Revenues	2022	% of Total Revenues	2021	% of Total Revenues
Selling, marketing and administrative	$ 763.2	25.5 %	$ 621.0	19.0 %	$ 239.6	14.1 %
Research and development	246.8	8.2 %	190.5	5.8 %	95.7	5.6 %
Amortization of intangible assets	204.8	6.8 %	132.5	4.1 %	27.4	1.6 %
Acquisition and integration costs	113.4	3.8 %	136.0	4.2 %	9.6	0.6 %
Other operating expenses	27.1	0.9 %	12.3	0.4 %	—	— %

Selling, Marketing and Administrative Expenses

Selling, marketing and administrative expenses for fiscal year 2023 increased by $142.2 million, or 22.9%, to $763.2 million from $621.0 million for the prior year, primarily due to the incremental impact of the Combinations, partially offset by freight expense due to lower sales and shipment volume and lower employee compensation costs.

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, primarily driven 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 higher employee-related costs.

Research and Development Expense

Research and development expense for fiscal year 2023 increased by $56.3 million, or 29.6%, to $246.8 million from $190.5 million for the prior year, primarily due to the incremental impact of the Combinations, as well as increased costs related to the development of Savanna, QuickVue OTC assays and Sofia products.

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.

Amortization of Intangible Assets

Amortization of intangible assets for fiscal years 2023, 2022 and 2021 was $204.8 million, $132.5 million and $27.4 million, respectively. The increases in amortization expense in fiscal year 2023 compared to fiscal year 2022 and fiscal year 2022 compared to fiscal year 2021 were primarily due to the Combinations.

Acquisition and Integration Costs

Acquisition and integration costs were $113.4 million, $136.0 million and $9.6 million for fiscal years 2023, 2022 and 2021, respectively. The decrease in costs in fiscal year 2023 compared to fiscal year 2022 was primarily due to acquisition costs attributable to the Combinations, partially offset by higher integration-related costs. The increase in costs in fiscal year 2022 compared to fiscal year 2021 was primarily due to acquisition and integration-related costs attributable to the Combinations. Costs for fiscal year 2021 were primarily related to the evaluation of new business development opportunities, including the Combinations.

Other Operating Expenses

Other operating expenses were $27.1 million and $12.3 million for fiscal years 2023 and 2022, respectively, which were primarily 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 2023, 2022 and 2021:

	Fiscal Year Ended				
(Dollars in millions)	**2023**	**2022**	**2021**	**% Change 2023 vs. 2022**	**% Change 2022 vs. 2021**
Interest expense, net	$ 147.6	$ 75.7	$ 5.8	95.0 %	N/M
Loss on extinguishment of debt	—	24.0	—	(100.0)%	N/M
Other expense (income), net	20.6	8.1	(0.1)	154.3 %	N/M

* N/M - Not meaningful

Interest Expense, Net

Interest expense, net was $147.6 million, $75.7 million and $5.8 million for fiscal years 2023, 2022 and 2021, respectively. The increases in interest expense, net in fiscal year 2023 compared to fiscal year 2022 and fiscal year 2022 compared to fiscal year 2021 were primarily related to the Term Loan under the Credit Agreement entered into in connection with the Combinations. See Part II, Item 8, “Financial Statements and Supplementary Data—Note 8. Borrowings” for more information related to our Term Loan.

Loss on Extinguishment of Debt

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

Other Expense (Income), Net

Other expense (income), net was $20.6 million, $8.1 million and $(0.1) million for fiscal years 2023, 2022 and 2021, respectively. The increase in Other expense (income), net in fiscal year 2023 compared to fiscal year 2022 was primarily related to (i) the release of tax reserves upon the settlement of certain U.S. federal tax matters, with an offsetting benefit recorded to income tax expense and (ii) net foreign currency losses. See Part II, Item 8, “Financial Statements and Supplementary Data—Note 6. Income Taxes” for more information related to our indemnification assets. The change in Other expense (income), net in fiscal year 2022 compared to 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.

Income Taxes

For fiscal years 2023 and 2022, we recognized income tax benefits of $19.0 million in relation to loss before taxes of $29.1 million and income tax provisions of $187.2 million in relation to income before taxes of $735.9 million, resulting in effective tax rates of 65.3% and 25.4%, respectively. For fiscal year 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to a decrease in our pre-acquisition U.S. federal reserves for uncertain tax positions due to settlement of certain tax matters partially offset by net operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances and Global Intangible Low-Taxed Income (“GILTI”). For fiscal year 2022, the effective tax rate was primarily impacted by income taxes owed in certain U.S. states, foreign income taxed at rates other than the applicable U.S. rate, and the deduction for foreign derived intangible income (“FDII”).

We recognized an income tax provision of $187.2 million, resulting in an effective tax rate of 25.4% for fiscal year 2022. This effective tax rate is comparable to the effective tax rate of 21.8% for fiscal year 2021. 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 FDII, partially offset by increases in non-deductible executive compensation, GILTI and acquisition-related costs. The Company will treat any U.S. tax on foreign earnings under GILTI as a current period expense when incurred.

Segment Results

We 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."

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 (loss) income before Interest expense, net, (Benefit from) provision for income taxes and depreciation and amortization and eliminates (i) certain non-operating income or expense items, and (ii) impacts of certain non-cash, unusual or other items that are included in Net (loss) income and that we do not consider indicative of our ongoing operating performance. See Part II, Item 8, "Financial Statements and Supplementary Data—Note 5. Segment and Geographic Information" for a reconciliation of Adjusted EBITDA by reportable segment to (Loss) income before income taxes.

North America

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

	Fiscal Year Ended				
(Dollars in millions)	2023	2022	2021	% Change 2023 vs. 2022	% Change 2022 vs. 2021
Total revenues	$ 1,877.1	$ 2,536.5	$ 1,500.2	(26) %	69 %
Adjusted EBITDA	$ 949.2	$ 1,614.6	$ 1,028.5	(41) %	57 %

Total revenues were $1,877.1 million for fiscal year 2023, compared to $2,536.5 million for fiscal year 2022. The decrease was primarily driven by lower demand for QuickVue and Sofia SARS Antigen assays, partially offset by incremental revenues of $433.8 million from the Combinations.

Total revenues were $2,536.5 million for fiscal year 2022, compared to $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 primarily driven by increased demand for QuickVue SARS Antigen assays and non-SARS related rapid tests, partially offset by a decrease in revenues for the Sofia SARS Antigen assay.

Adjusted EBITDA was $949.2 million for fiscal year 2023, compared to $1,614.6 million for fiscal year 2022. The decrease was primarily driven by lower demand for QuickVue and Sofia SARS Antigen assays, partially offset by decreased distribution costs and approximately $160 million of incremental impact of the Combinations.

Adjusted EBITDA was $1,614.6 million for fiscal year 2022, compared to $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 primarily driven by increased revenues, partially offset by increased distribution and selling costs.

EMEA

Total revenues and Adjusted EBITDA for EMEA were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2023	2022	2021	% Change 2023 vs. 2022	% Change 2022 vs. 2021
Total revenues	$ 327.3	$ 206.8	$ 69.6	58 %	197 %
Adjusted EBITDA	$ 58.3	$ 31.7	$ 28.1	84 %	13 %

Total revenues were $327.3 million for fiscal year 2023, compared to $206.8 million for fiscal year 2022. The increase was primarily driven by incremental revenues of $110.1 million from the Combinations, partially offset by a decrease in Point of Care revenue.

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

Adjusted EBITDA was $58.3 million for fiscal year 2023, compared to $31.7 million for fiscal year 2022. The increase was primarily driven by incremental revenues from the Combinations, partially offset by lower Point of Care revenue and increased selling and distribution costs.

Adjusted EBITDA was $31.7 million for fiscal year 2022, compared to $28.1 million for fiscal year 2021. The increase was primarily driven by the impact of the Combinations, which contributed approximately $18 million to Adjusted EBITDA, partially offset by lower revenues and increased selling costs.

China

Total revenues and Adjusted EBITDA for China were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2023	2022	2021	% Change 2023 vs. 2022	% Change 2022 vs. 2021
Total revenues	$ 310.1	$ 220.0	$ 58.0	41 %	279 %
Adjusted EBITDA	$ 129.1	$ 104.1	$ 24.1	24 %	332 %

Total revenues were $310.1 million for fiscal year 2023, compared to $220.0 million for fiscal year 2022. The increase was primarily driven by incremental revenues of $95.0 million from the Combinations, partially offset by lower Point of Care revenue, primarily related to decreased demand for QuickVue SARS Antigen assays.

Total revenues were $220.0 million for fiscal year 2022, compared to $58.0 million for fiscal year 2021. The increase was primarily driven by the impact of the Combinations, which contributed $161.3 million to Total revenues.

Adjusted EBITDA was $129.1 million for fiscal year 2023, compared to $104.1 million for fiscal year 2022. The increase was primarily driven by approximately $29 million of incremental impact of the Combinations, partially offset by lower Point of Care revenue and a shift in product mix.

Adjusted EBITDA was $104.1 million for fiscal year 2022, compared to $24.1 million for fiscal year 2021. The increase was primarily driven by the impact of the Combinations of approximately $81 million.

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)	2023	2022	2021	% Change 2023 vs. 2022	% Change 2022 vs. 2021
Total revenues	$ 483.3	$ 302.7	$ 70.8	60 %	328 %
Adjusted EBITDA	$ 116.3	$ 92.7	$ 43.0	25 %	116 %

Total revenues were $483.3 million for fiscal year 2023, compared to $302.7 million for fiscal year 2022. The increase was primarily driven by incremental revenues of $177.1 million from the Combinations and higher Labs revenue, partially offset by lower Point of Care revenue.

Total revenues were $302.7 million for fiscal year 2022, compared to $70.8 million for fiscal year 2021. The increase was primarily driven by the impact of the Combinations, which contributed $250.5 million to Total revenues, partially offset by lower Point of Care revenue, driven by lower demand for QuickVue SARS Antigen and Sofia assays.

Adjusted EBITDA was $116.3 million for fiscal year 2023, compared to $92.7 million for fiscal year 2022. The increase was primarily driven by approximately $37 million of incremental impact of the Combinations, partially offset by lower Point of Care revenue.

Adjusted EBITDA was $92.7 million for fiscal year 2022, compared to $43.0 million for fiscal year 2021. The increase was primarily driven by the impact of the Combinations, which contributed approximately $63 million to Adjusted EBITDA, partially offset by lower revenues.

Liquidity and Capital Resources

As of December 31, 2023 and January 1, 2023, the principal sources of liquidity consisted of the following:

(Dollars in millions)	December 31, 2023	January 1, 2023
Cash and cash equivalents	$ 118.9	$ 292.9
Marketable securities, current	48.4	52.1
Marketable securities, non-current	7.4	21.0
Total cash, cash equivalents and marketable securities	$ 174.7	$ 366.0
Amount available to borrow under the Revolving Credit Facility	$ 787.1	$ 786.9
Working capital including cash and cash equivalents and marketable securities, current	$ 476.7	$ 568.1

As of December 31, 2023, we had $118.9 million in Cash and cash equivalents, a $174.0 million decrease from January 1, 2023. 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. We believe our organizational structure allows us the necessary flexibility to move funds throughout our subsidiaries to meet our operational working capital needs.

Our Credit Agreement consists of a $2,750.0 million Term Loan and an $800.0 million Revolving Credit Facility. As of December 31, 2023 and January 1, 2023, there were no amounts outstanding under the Revolving Credit Facility. As of December 31, 2023, letters of credit issued under the Revolving Credit Facility totaled $12.9 million, which reduced the available amount under the Revolving Credit Facility to $787.1 million. The Term Loan and the Revolving Credit Facility will mature on May 27, 2027. In fiscal year 2023, we made $226.7 million in payments on our Term Loan, including a voluntary prepayment of $20.0 million. Refer to Part II, Item 8, “Financial Statements and Supplementary Data—Note 8. Borrowings” for further information.

On March 31, 2023, we entered into an amendment to our existing receivables purchase agreement (the “RPA”), by and among Ortho-Clinical Diagnostics US FinanceCo I, LLC (“Ortho FinanceCo I”), as Seller, our wholly owned receivables financing subsidiary, Wells Fargo Bank, N.A., as administrative agent (the “Agent”), Ortho-Clinical Diagnostics, Inc., as the Master Servicer and as an Originator (“Ortho Inc.”), Quidel Corporation, as an Originator, and certain Purchasers. Under the RPA, as amended, Ortho FinanceCo I may sell receivables in amounts up to a $150.0 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 Inc., 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. We have also provided a performance guaranty for the benefit of Ortho FinanceCo I to cause the due and punctual performance by Ortho Inc. of its obligations as Master Servicer.

Our Stock Repurchase Program allows us to repurchase up to $300.0 million of our common stock through August 17, 2024. The Stock Repurchase Program does not obligate us 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 us in our

discretion and depend on a variety of factors, including legal requirements, price and economic and market conditions. For the fiscal year ended December 31, 2023, we repurchased 120,000 shares of outstanding common stock under the Stock Repurchase Program for approximately $7.2 million. The repurchased shares were retired and returned to the status of authorized but unissued shares of our common stock. As of December 31, 2023, we had approximately $218.4 million available under the Stock Repurchase Program. Refer to Part II, Item 5, “Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities” for further information.

Our investment portfolio includes marketable debt securities, which are subject to changes in fair value as a result of interest rate fluctuations and other market factors. Our investment policy establishes limits on the amount and time to maturity of investments with any institution. The investment policy also requires that investments are only entered into with corporate and financial institutions that meet high credit quality standards. Refer to Part II, Item 8, “Financial Statements and Supplementary Data—Note 13. Fair Value Measurements.”

Capital Expenditures

Annual capital expenditures, net of proceeds from government assistance allocated to fixed assets, were approximately $196 million, $123 million and $256 million in fiscal years 2023, 2022 and 2021, respectively. We continue to make capital expenditures in connection with the expansion of our manufacturing capabilities and other facility-related activities.

Cash Flow Summary

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
Net cash provided by operating activities	$ 280.2	$ 885.3	$ 805.9
Net cash used for investing activities	(187.6)	(1,644.2)	(319.5)
Net cash (used for) provided by financing activities	(265.8)	252.0	(173.1)
Effect of exchange rates on cash	(1.2)	(2.0)	(0.4)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (174.4)	$ (508.9)	$ 312.9

Fiscal Year Ended December 31, 2023

Cash provided by operating activities was $280.2 million for fiscal year 2023, and reflected a net loss of $10.1 million and non-cash adjustments of $485.2 million, primarily associated with depreciation and amortization, stock-based compensation expense and accretion of interest on deferred consideration. In addition, we benefited from collections on accounts receivables, which contributed $160.0 million to Cash provided by operating activities, offset by other changes in working capital, including $211.6 million of cash outflows for inventories.

Cash used for investing activities was $187.6 million for fiscal year 2023, and was primarily related to $209.3 million in purchases of property, equipment, investments and intangibles. We also purchased $60.1 million and sold $78.3 million of marketable securities during fiscal year 2023.

Cash used for financing activities was $265.8 million for fiscal year 2023, and was primarily related to payments on long-term borrowings of $228.0 million, payments of deferred consideration of $30.3 million and payments of tax withholdings related to vesting of stock-based awards of $13.5 million.

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 the unwind 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, 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 Part II, Item 8, “Financial Statements and Supplementary Data—Note 2. Business Combination” 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 (as defined in this Annual Report) and pursuant to stock option exercises. Refer to Part II, Item 8, “Financial Statements and Supplementary Data—Note 10. Stockholders’ Equity.”

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 and lease obligations;
- acquisitions of property, equipment and other fixed assets in support of our manufacturing facility expansions;
- 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 2023, we transferred $154.6 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.

In January 2023, we entered into a lease for warehouse space in the U.S. that has not yet commenced, with total lease payments of approximately $36 million. This lease is expected to commence during the first half of 2024 with a lease term of five years.

Contractual Obligations and Off-Balance Sheet Arrangements

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. Information regarding our obligations relating to debt, income taxes, lease arrangements, purchase obligations and licensing arrangements are provided in Part II, Item 8, “Financial Statements and Supplementary Data—Note 8. Borrowings,” “—Note 6. Income Taxes,” “—Note 9. Leases” and “—Note 12. Commitments and Contingencies,” respectively.

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our financial condition or results of operations.

Recent Accounting Pronouncements

Information about recently adopted and proposed accounting pronouncements is included in Part II, Item 8, “Financial Statements and Supplementary Data—Note 1. Basis of Presentation and Summary of Significant Accounting Policies.”

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 the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses. Our critical accounting estimates are those that significantly affect our financial condition and results of operations and require the most difficult, subjective or complex judgments, often because of the need to make estimates about the effect of matters that are inherently uncertain. Because of this uncertainty, actual results may vary from these estimates.

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. These rebates are presented as either an offset to trade accounts receivable or a liability based on forms of settlement. 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 $31.3 million of our rebate reserves at December 31, 2023. Our total rebate reserve was $75.6 million at December 31, 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. For our annual evaluation for impairment of goodwill as of October 2, 2023, we bypassed the qualitative assessment and proceeded directly to the quantitative goodwill impairment test for all reporting units. This quantitative analysis required us to make estimates and assumptions in order to calculate the fair value of our reporting units. We utilized the values separately derived from both income and market approach valuation techniques to develop an overall estimate of reporting unit fair values. Under the income approach, we calculated the fair value of our reporting units based on estimated future discounted cash flows which required significant assumptions surrounding projected revenue growth rates, projected EBITDA margins and discount rates. Under the market approach, we estimated the fair value based on market multiples of our revenue and EBITDA. In all instances, the estimated fair values of our reporting units exceeded their carrying values and consequently did not result in an impairment. The excess of the estimated fair value over carrying value (expressed as a percentage of carrying value for the respective reporting unit) for our North America, EMEA, Latin America, Japan and Asia Pacific reporting units as of the testing date ranged from approximately 8% to 70%. The excess of the estimated fair value over carrying value for our China reporting unit was approximately 170%. To evaluate the sensitivity of the fair value calculations used in the goodwill impairment test, the Company applied a hypothetical 5% decrease to the fair values of each reporting unit and compared those hypothetical values to the reporting unit carrying values. Based on this hypothetical 5% decrease, the excess of the estimated fair value over carrying value (expressed as a percentage of carrying value for the respective reporting unit) for each of our reporting units ranged from approximately 3% to approximately 160%.

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. A valuation allowance may be established to reduce our deferred tax assets to the amount that is considered more likely than not to be realized through the generation of future taxable income and other tax planning opportunities. As of December 31, 2023, we had a valuation allowance of $274.7 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 Part II, Item 8, "Financial Statements and Supplementary Data—Note 6. Income Taxes" 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 (Loss) Income.

Inventory Valuations

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 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 $4.0 million per year before considering the impact of derivative instruments. For further discussion of the risks related to our Credit Agreement, see "Risk Factors—Risks Relating to Corporate Finance—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" 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 entered into interest rate swap contracts, commencing on December 30, 2022, with a total notional value of $1.3 billion, which increased to $1.8 billion on December 29, 2023, to hedge future interest rate exposures on variable rate debt, including the Revolving Credit Facility and Term Loan.

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 continue to evaluate our investments, our cash equivalents as of December 31, 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 39% of our Total revenues for the fiscal year ended December 31, 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 comprehensive income of $50.4 million and a comprehensive loss of $69.8 million for the fiscal years ended December 31, 2023 and January 1, 2023, respectively. 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 Australian Dollar, Brazilian Real, British Pound, Canadian Dollar, Chilean Peso, Chinese Yuan/Renminbi, Colombian Peso, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Philippine Peso, South Korean Won, Swiss Franc, Danish Krone, Czech Koruna and Thai Baht. 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 level of operations and 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 can affect our results of operations. During the fiscal years ended December 31, 2023 and January 1, 2023, we recorded net foreign currency exchange losses of $2.6 million and $6.0 million, respectively. 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 have entered into and may in the future 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 a total notional amount of $1,252.2 million as of December 31, 2023, with maturity dates through December 2024. Foreign currency forward contracts that qualified and were designated for hedge accounting are recorded at their fair value as of December 31, 2023 and the pre-tax unrealized loss of $6.7 million is reported as a component of Other comprehensive income (loss) ("OCI"), 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 losses upon settlement recognized in earnings during the fiscal year ended December 31, 2023 were $6.2 million. 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.

A sensitivity to changes in the value of the U.S. dollar on foreign currency denominated derivatives and investments indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2023, (Loss) income before income taxes would have declined by approximately $4.4 million in fiscal year 2023. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in the Company's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statements of Cash Flows.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The

unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within OCI, and remain in Accumulated other comprehensive loss (“AOCI”) until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in OCI. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

See Part II, Item 8, “Financial Statements and Supplementary Data—Note 14. Derivative Instruments and Hedging Activities” 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 December 31, 2023 and January 1, 2023, the related consolidated statements of (loss) income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 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 December 31, 2023 and January 1, 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 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 29, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

	Reserve for contractual rebates
Description of the Matter	As described in Note 1 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 December 31, 2023, the Company recognized an allowance on accounts receivable of $ 31.3 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.

/s/ Ernst & Young LLP

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

San Diego, California

February 29, 2024

QUIDELORTHO CORPORATION

CONSOLIDATED BALANCE SHEETS

(In millions, except par value)

	December 31, 2023	January 1, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 118.9	$ 292.9
Marketable securities	48.4	52.1
Accounts receivable, net	303.3	453.9
Inventories	577.8	524.1
Prepaid expenses and other current assets	262.1	252.1
Total current assets	1,310.5	1,575.1
Property, plant and equipment, net	1,443.8	1,339.0
Marketable securities	7.4	21.0
Right-of-use assets	169.6	181.0
Goodwill	2,492.0	2,476.8
Intangible assets, net	2,934.3	3,123.8
Deferred tax asset	25.9	16.4
Other assets	179.6	122.7
Total assets	$ 8,563.1	$ 8,855.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 294.8	$ 283.3
Accrued payroll and related expenses	84.8	139.2
Income tax payable	11.1	51.6
Current portion of borrowings	139.8	207.5
Other current liabilities	303.3	325.4
Total current liabilities	833.8	1,007.0
Operating lease liabilities	172.8	186.4
Long-term borrowings	2,274.8	2,430.8
Deferred tax liability	192.2	213.2
Other liabilities	83.6	83.8
Total liabilities	3,557.2	3,921.2
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $ 0.001 par value per share; 5.0 shares authorized; none issued or outstanding at December 31, 2023 and January 1, 2023	—	—
Common stock, $ 0.001 par value per share; 126.2 shares authorized; 66.7 and 66.4 shares issued and outstanding at December 31, 2023 and January 1, 2023, respectively	0.1	—
Additional paid-in capital	2,848.0	2,804.3
Accumulated other comprehensive loss	(30.0)	(67.6)
Retained earnings	2,187.8	2,197.9
Total stockholders' equity	5,005.9	4,934.6
Total liabilities and stockholders' equity	$ 8,563.1	$ 8,855.8

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF (LOSS) INCOME

(In millions, except per share data)

	Fiscal Year Ended		
	2023	2022	2021
Total revenues	$ 2,997.8	$ 3,266.0	$ 1,698.6
Cost of sales, excluding amortization of intangibles	1,503.4	1,330.0	420.3
Selling, marketing and administrative	763.2	621.0	239.6
Research and development	246.8	190.5	95.7
Amortization of intangible assets	204.8	132.5	27.4
Acquisition and integration costs	113.4	136.0	9.6
Other operating expenses	27.1	12.3	—
Operating income	139.1	843.7	906.0
Interest expense, net	147.6	75.7	5.8
Loss on extinguishment of debt	—	24.0	—
Other expense (income), net	20.6	8.1	(0.1)
(Loss) income before income taxes	(29.1)	735.9	900.3
(Benefit from) provision for income taxes	(19.0)	187.2	196.1
Net (loss) income	$ (10.1)	$ 548.7	$ 704.2
Basic (loss) earnings per share	$ (0.15)	$ 9.66	$ 16.74
Diluted (loss) earnings per share	$ (0.15)	$ 9.56	$ 16.43
Weighted-average shares outstanding - basic	66.8	56.8	42.1
Weighted-average shares outstanding - diluted	66.8	57.4	42.9

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In millions)

	Fiscal Year Ended		
	2023	2022	2021
Net (loss) income	$ (10.1)	$ 548.7	$ 704.2
Other comprehensive income (loss)			
Changes in cumulative translation adjustment, net of tax	50.4	(69.8)	(1.6)
Changes in unrealized gains (losses) from investments, net of tax	0.5	(0.4)	(0.1)
Changes from pension and other post-employment benefits, net of tax	(2.0)	0.7	—
Changes in unrealized gains (losses) from cash flow hedges, net of tax:			
Net unrealized gains on derivative instruments	12.6	6.7	0.1
Reclassification of net realized (gains) losses on derivative instruments included in net income	(23.9)	(5.2)	2.4
Total change in unrealized (losses) gains from cash flow hedges, net of tax	(11.3)	1.5	2.5
Comprehensive income	$ 27.5	$ 480.7	$ 705.0

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In millions)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
	Shares	Par				
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
Issuance of common stock under equity compensation plans	0.6	0.1	13.5	—	—	13.6
Stock-based compensation expense	—	—	50.9	—	—	50.9
Tax withholdings related to vesting of stock-based awards	(0.2)	—	(13.5)	—	—	(13.5)
Repurchases of common stock	(0.1)	—	(7.2)	—	—	(7.2)
Other comprehensive income, net of tax	—	—	—	37.6	—	37.6
Net loss	—	—	—	—	(10.1)	(10.1)
Balance at December 31, 2023	66.7	$ 0.1	$ 2,848.0	$ (30.0)	$ 2,187.8	$ 5,005.9

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Fiscal Year Ended		
	2023	**2022**	**2021**
OPERATING ACTIVITIES:			
Net (loss) income	$ (10.1)	$ 548.7	$ 704.2
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	457.2	283.6	52.7
Stock-based compensation expense	51.6	48.4	25.4
Net change in operating lease right-of-use assets and liabilities	—	18.4	3.0
Payment of accreted interest on contingent and deferred consideration	(9.7)	(10.4)	(8.2)
Loss on extinguishment of debt	—	24.0	—
Unwind inventory fair value adjustment	—	60.6	—
Other non-cash, net	(13.9)	(34.8)	31.6
Changes in assets and liabilities:			
Accounts receivable	160.0	150.2	118.9
Inventories	(211.6)	(116.9)	(85.0)
Prepaid expenses and other current and non-current assets	(26.9)	(26.2)	(13.3)
Accounts payable	3.0	23.5	10.4
Accrued payroll and related expenses	(53.9)	18.2	5.0
Income taxes payable	(59.6)	(26.8)	(66.7)
Other current and non-current liabilities	(5.9)	(75.2)	27.9
Net cash provided by operating activities	280.2	885.3	805.9
INVESTING ACTIVITIES			
Acquisitions of property, equipment, investments and intangibles	(209.3)	(140.9)	(292.8)
Acquisition of businesses, net of cash and restricted cash acquired	—	(1,511.4)	—
Proceeds from government assistance allocated to fixed assets	13.5	18.4	36.9
Purchases of marketable securities	(60.1)	(63.7)	(67.4)
Proceeds from sale of marketable securities	78.3	53.4	3.8
Other payments	(10.0)	—	—
Net cash used for investing activities	(187.6)	(1,644.2)	(319.5)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	11.6	26.4	7.6
Short-term borrowings, net	1.6	—	—
Proceeds from long-term borrowings, net of debt issuance costs	—	2,734.5	—
Payments on long-term borrowings and extinguishment costs	(228.0)	(2,388.3)	(0.3)
Payments of tax withholdings related to vesting of stock-based awards	(13.5)	(8.6)	(37.1)
Repurchases of common stock	(7.2)	(74.3)	(103.5)
Principal payments of acquisition contingent consideration	—	(4.2)	(4.7)
Principal payments of deferred consideration	(30.3)	(33.5)	(35.1)
Net cash (used for) provided by financing activities	(265.8)	252.0	(173.1)
Effect of exchange rates on cash	(1.2)	(2.0)	(0.4)
Net (decrease) increase in cash, cash equivalents and restricted cash	(174.4)	(508.9)	312.9
Cash, cash equivalents and restricted cash at beginning of period	293.9	802.8	489.9
Cash, cash equivalents and restricted cash at end of period	$ 119.5	$ 293.9	$ 802.8
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid during the period for interest	$ 150.0	$ 95.1	$ —
Cash paid during the period for income taxes	$ 86.6	$ 264.8	$ 235.6
Purchase of property, equipment and intangibles by incurring current liabilities	$ 40.6	$ 40.4	$ 10.5
Transfer of instrument inventories to fixed assets	$ 154.6	$ 73.7	$ —
Reduction of other current liabilities upon issuance of restricted share units	$ 1.9	$ 4.6	$ 2.0

See accompanying notes.

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

Organization and Business

The Company's vision is to advance diagnostics to power a healthier future. With its expertise in immunoassay and molecular testing, clinical chemistry and transfusion medicine, the Company aims to provide clarity to clinicians and patients to help create better health outcomes. 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.

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. Business Combination" for further information regarding the Combinations.

Basis of Presentation

The accompanying Consolidated Financial Statements of the Company have been prepared in accordance with 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 2023, 2022 and 2021, the Company's fiscal years ended on December 31, 2023, January 1, 2023 and January 2, 2022, respectively. Fiscal years 2023, 2022 and 2021 were 52 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, returns, 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.

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 and government debt securities, corporate asset-backed securities and commercial paper. 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 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 (Loss) 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. Revenue"). 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 $ 91.8 million and $ 89.1 million at December 31, 2023 and January 1, 2023, respectively, of which the reserve related to contract rebates was $ 75.6 million and $ 73.5 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 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. The Company's annual impairment assessment date is the first day of the fourth quarter of the fiscal year.

The chief operating decision maker ("CODM") reviews the Company's performance and allocates resources based on 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." Each of these six operating segments is considered a reporting unit for the purpose of allocating goodwill and performing the annual goodwill impairment assessment.

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 2023, the Company bypassed the qualitative assessment and proceeded directly to the quantitative goodwill impairment test for all reporting units as of the beginning of the fiscal fourth quarter. In all instances, the estimated fair values of the Company's reporting units exceeded their carrying values and consequently did not result in an impairment.

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.

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 the Company is 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.

The Company generates 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. In fiscal years 2022 and 2021, due to a lack of history on which to base an estimate of products to be returned from the retailers, the Company established a reserve based on an estimate of total inventory remaining at our retailers which was subject to return. During fiscal year 2023, the Company concluded that it had developed sufficient historical experience regarding the pattern in customer returns to be able to estimate the amount of consideration to which the Company expects to be entitled, excluding consideration for the products expected to be returned. Amounts received or receivable that are expected to be returned are recognized as a refund liability, which is included in Other current liabilities. The refund liability is estimated utilizing historical sale and return rates over the period during which customers have a right of return, taking into account available information on competitive products and contract changes. The refund liability is remeasured at each reporting period to reflect changes in assumptions about expected returns. Revenues from sales to retail customers amounted to approximately 3 % of Total revenues for fiscal year

2023. The impact from this change in estimate is approximately $ 0.3 million and is not material to the Company's Consolidated Financial Statements.

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. 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 (Loss) 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. Variable lease revenue and fixed lease revenue represented approximately 4 % and 1 %, respectively, of the Company's Total revenues for fiscal year 2023. Revenue allocated to the instrument was not material for fiscal years 2022 and 2021.

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 $ 13.5 million and $ 18.4 million during fiscal years 2023 and 2022, respectively, which were recorded as reductions 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 (Loss) Income. Shipping and handling costs were $ 124.1 million, $ 104.9 million and $ 29.3 million for fiscal years 2023, 2022 and 2021, respectively.

Advertising Costs

Advertising costs are expensed as incurred and included in Selling, marketing and administrative expense in the accompanying Consolidated Statements of (Loss) Income. Advertising costs were $ 15.1 million, $ 26.8 million and $ 13.7 million for fiscal years 2023, 2022 and 2021, 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. Accordingly, 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 Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures, which requires that the valuation of assets and liabilities subject to fair value measurements be classified and disclosed by the Company in one of the following three categories:

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

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

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

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable and accrued liabilities approximate their fair values due to their short-term nature.

Stock-based Compensation

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 (Loss) 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

There have been no accounting pronouncements issued or adopted during fiscal year 2023 that are expected to have a material impact on the Company's 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 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 $ 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 proceeds from the Financing.

The Combinations have been accounted for as a business combination, which requires that assets acquired and liabilities assumed be recognized at their fair value as of the date of the consummation of the Combinations, with Quidel considered the accounting and the legal acquirer. The assessment of the fair value of assets acquired and liabilities assumed was finalized in fiscal year 2023. The measurement period adjustments reflected in fiscal year 2023 resulted from finalization of tax related matters. The related impact to net earnings that would have been recognized in previous periods if the adjustments were recognized as of the date of the consummation of the Combinations is immaterial to the Company's Consolidated Financial Statements.

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below:

(In millions)	Amounts Recognized as of Acquisition Date (As Previously Reported) [1]	Measurement Period Adjustments	Purchase Price Allocation
Cash and cash equivalents	$ 234.5	$ —	$ 234.5
Accounts receivable	240.6	—	240.6
Inventories [2]	384.4	—	384.4
Property, plant and equipment	948.9	—	948.9
Goodwill	2,178.4	(19.9)	2,158.5
Intangible assets	3,168.0	—	3,168.0
Prepaid expenses and other assets	271.7	(1.3)	270.4
Total assets	7,426.5	(21.2)	7,405.3
Accounts payable	(135.0)	—	(135.0)
Accrued payroll and related expenses	(81.1)	—	(81.1)
Long-term borrowings, including current portion [3]	(2,268.4)	—	(2,268.4)
Deferred tax liability	(278.4)	18.3	(260.1)
Other current and non-current liabilities	(372.5)	2.9	(369.6)
Total liabilities	(3,135.4)	21.2	(3,114.2)
Total purchase consideration	$ 4,291.1	$ —	$ 4,291.1

(1) As reported in the Company's Annual Report on Form 10-K for the fiscal year ended January 1, 2023.

(2) Includes an estimated fair value adjustment to inventory of $ 61.7 million, which was fully recognized in the Consolidated Statements of (Loss) Income in fiscal year 2022.

(3) 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.

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 assignment of goodwill by reportable segment at the acquisition date is as follows (in millions):

North America	$	1,202.1
EMEA		365.9
China		120.3
Other		470.2
	$	2,158.5

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 [1]	20 years	$	1,907.0
Developed technology [2]	15 years		888.0
Trademarks [2]	15 years		373.0
		$	3,168.0

(1) The fair value 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.

(2) The fair value 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 (Loss) 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 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;

- decreases in interest expense 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 loss on extinguishment of debt from Ortho's results in fiscal year 2021 and the reclassification of loss on extinguishment of debt in fiscal years 2021 and 2022;
- the reclassification of expense related to the accelerated vesting of certain stock awards of Ortho's former chief executive officer; and
- tax impacts related to the above adjustments.

From the acquisition date 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 (loss) 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 and unvested RSUs. 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.

The following table presents the calculation of the weighted-average shares used in computing basic and diluted EPS in the respective periods:

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
Basic weighted-average shares of common stock outstanding	66.8	56.8	42.1
Dilutive potential shares issuable from stock options and RSUs (1)	—	0.6	0.8
Diluted weighted-average shares of common stock outstanding	66.8	57.4	42.9

(1) In fiscal year 2023, all potential shares of common stock issuable for stock options and RSUs were excluded from the dilutive calculations above because the effect of including them would have been anti-dilutive. The dilutive effect of potential shares of common stock issuable for stock options and RSUs on the weighted-average number of shares of common stock outstanding would have been as follows:

	Fiscal Year Ended
(In millions)	**2023**
Basic weighted-average shares of common stock outstanding	66.8
Dilutive potential shares issuable from stock options and RSUs	0.5
Diluted weighted-average shares of common stock outstanding	67.3

Stock options and RSUs where the combined exercise price and unrecognized stock-based compensation was greater than the average market price for the Company's common stock were not included in the computations of diluted weighted-average shares because the effect would have been anti-dilutive. These stock options and RSUs represented 1.6 million, 0.9 million and 0.1 million shares of common stock for fiscal years 2023, 2022 and 2021, respectively.

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 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 December 31, 2023 and January 1, 2023 was $ 46.2 million and $ 49.6 million, respectively.

The contract asset balance consisted of the following components, all of which related to agreements acquired by the Company in connection with the Combinations:

- a customer supply agreement under which the difference between the timing of invoicing and revenue recognition resulted in a contract asset of $ 1.9 million and $ 6.8 million as of December 31, 2023 and January 1, 2023, respectively;
- 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 $ 41.8 million and $ 38.5 million as of December 31, 2023 and January 1, 2023, respectively; and
- one of the Company's contract manufacturing agreements that recognizes revenue as the products are manufactured resulted in a contract asset of $ 2.5 million and $ 4.3 million as of December 31, 2023 and January 1, 2023, respectively.

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 years 2023 and 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 $ 36.8 million and $ 76.4 million as of December 31, 2023 and January 1, 2023, respectively. 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 $ 13.9 million and $ 9.4 million as of December 31, 2023 and January 1, 2023, respectively, and was included in Other liabilities in the Consolidated Balance Sheets. The amount of deferred revenue as of January 1, 2023 that was recorded in Total revenues during fiscal year 2023 was $ 72.1 million. The amount of deferred revenue as of January 2, 2022 that was recorded in Total revenues during fiscal year 2022 was not material.

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 Joint Business agreement. The Company's portion of the pre-tax net profit shared under the Joint Business was $ 47.3 million and $ 18.6 million during fiscal years 2023 and 2022, respectively. These amounts included the Company's portion of the pre-tax net profit of $ 21.4 million and $ 11.1 million during fiscal years 2023 and 2022, respectively, 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 (Loss) Income. The Company's portion of the pre-tax net profit also included revenue from collaboration and royalty agreements of $ 26.0 million and $ 7.5 million during fiscal years 2023 and 2022, respectively, which is presented on a net basis within Total revenues.

Disaggregation of Revenue

The following table summarizes Total revenues by business unit:

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
Labs	$ 1,425.4	$ 820.2	$ 44.8
Transfusion Medicine	648.5	393.8	—
Point of Care	892.2	1,955.3	1,453.3
Molecular Diagnostics	31.7	96.7	200.5
Total revenues	$ 2,997.8	$ 3,266.0	$ 1,698.6

Concentration of Revenue and Credit Risk

For fiscal year 2023, no customer individually accounted for more than 10% of Total revenues. Customers that accounted for 10% or more of the Company's Total revenues for fiscal years 2022 and 2021 were as follows:

	Fiscal Year Ended	
	2022	2021
Customer A	20 %	1 %
Customer B	11 %	24 %
	31 %	25 %

As of December 31, 2023 and January 1, 2023, customers with balances due in excess of 10% of Accounts receivable, net totaled $ 63.5 million and $ 161.9 million, respectively. Revenue related to our respiratory products accounted for 24 %, 57 % and 81 % of Total revenues for fiscal years 2023, 2022 and 2021, respectively.

Note 5. Segment and Geographic Information

The Company operates 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."

Total revenues by reportable segment are as follows:

	Fiscal Year Ended		
(In millions)	2023	2022	2021
North America	$ 1,877.1	$ 2,536.5	$ 1,500.2
EMEA	327.3	206.8	69.6
China	310.1	220.0	58.0
Other	483.3	302.7	70.8
Total revenues	$ 2,997.8	$ 3,266.0	$ 1,698.6

The following table sets forth Adjusted EBITDA by segment and the reconciliations to (Loss) income before income taxes for fiscal years 2023, 2022 and 2021:

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
North America	$ 949.2	$ 1,614.6	$ 1,028.5
EMEA	58.3	31.7	28.1
China	129.1	104.1	24.1
Other	116.3	92.7	43.0
Total segment Adjusted EBITDA	1,252.9	1,843.1	1,123.7
Corporate [1]	(529.7)	(512.1)	(152.9)
Interest expense, net	(147.6)	(75.7)	(5.8)
Depreciation and amortization	(457.2)	(283.6)	(52.7)
Acquisition and integration costs	(113.4)	(136.0)	(9.6)
Tax indemnification expense	(12.6)	(0.3)	—
Amortization of deferred cloud computing implementation costs	(9.2)	(5.4)	(3.7)
Impairment of long-lived assets	(4.5)	(2.8)	—
(Loss) gain on investments	(3.6)	(5.8)	1.5
EU medical device regulation transition costs [2]	(2.5)	(1.5)	—
Unwind inventory fair value adjustment	—	(60.6)	—
Loss on extinguishment of debt	—	(24.0)	—
Employee compensation charges	—	(3.2)	—
Derivative mark-to-market gain	—	4.4	—
Other adjustments	(1.7)	(0.6)	(0.2)
(Loss) income before income taxes	$ (29.1)	$ 735.9	$ 900.3

(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 the Company'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)	**December 31, 2023**	**January 1, 2023**	**2023**	**2022**	**2021**
Domestic	$ 1,024.5	$ 983.0	$ 1,829.4	$ 2,451.7	$ 1,415.5
Foreign	419.3	356.0	1,168.4	814.3	283.1
Total	$ 1,443.8	$ 1,339.0	$ 2,997.8	$ 3,266.0	$ 1,698.6

Note 6. Income Taxes

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

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
Current:			
Federal	$ (49.3)	$ 162.2	$ 148.8
State	(1.6)	48.8	42.4
Foreign	36.4	17.6	2.3
Total current provision	(14.5)	228.6	193.5
Deferred:			
Federal	8.5	(31.9)	7.2
State	(3.6)	(9.3)	(2.6)
Foreign	(9.4)	(0.2)	(2.0)
Total deferred (benefit) provision	(4.5)	(41.4)	2.6
(Benefit from) provision for income taxes	$ (19.0)	$ 187.2	$ 196.1

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

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
United States	$ (163.9)	$ 672.1	$ 891.2
Foreign	134.8	63.8	9.1
(Loss) income before income taxes	$ (29.1)	$ 735.9	$ 900.3

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 31, 2023 and January 1, 2023 are shown below:

(In millions)	**December 31, 2023**	**January 1, 2023**
Deferred tax assets:		
Lease liability	$ 47.2	$ 51.4
Allowance for returns and discounts	42.3	45.9
Inventory reserve	14.0	34.1
Stock-based compensation	15.8	14.6
Tax loss, interest expense and credit carryforwards	603.8	565.3
Research & development expenses	75.9	50.7
Employee related obligations	6.0	19.9
Other, net	10.8	16.1
Total deferred tax assets	815.8	798.0
Valuation allowance for deferred tax assets	(274.7)	(251.3)
Total deferred tax assets, net of valuation allowance	541.1	546.7
Deferred tax liabilities:		
Right-of-use assets	(38.9)	(43.8)
Intangible assets	(554.2)	(590.2)
Property, plant and equipment	(114.3)	(109.5)
Total deferred tax liabilities	(707.4)	(743.5)
Net deferred tax liabilities	$ (166.3)	$ (196.8)

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 December 31, 2023, January 1, 2023 and January 2, 2022, 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 $ 274.7 million as of December 31, 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 credits in 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 December 31, 2023, the Company had U.S. federal net operating loss ("NOL") carryforwards of $ 792.5 million, of which $ 304.1 million are subject to expiration through 2037 and $ 488.4 million are not subject to expiration. In addition, the Company has state NOLs of approximately $ 512.0 million, which will expire in years 2024 through 2043. As of December 31, 2023, the Company had U.S. federal research credit carryforwards of $ 26.7 million and federal foreign tax credits of $ 3.2 million, which will begin to expire in 2034 and 2028, respectively. In addition, the Company had state research credits of $ 16.2 million and state business credit carryforwards of $ 25.6 million, of which none expire. As of December 31, 2023, the Company had $ 560.7 million of NOL carryforwards in certain non-U.S. jurisdictions, net of uncertain tax positions. Of these, $ 296.6 million have no expiration and the remaining $ 264.1 million will expire in years through 2040.

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 on 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)	**2023**	**2022**	**2021**
Tax (benefit) expense at statutory tax rate	$ (6.1)	$ 154.5	$ 189.1
State tax (benefit) expense, net of federal tax	(2.8)	29.3	30.1
Foreign income taxed at rates other than the applicable U.S. rate	(23.0)	(27.5)	—
Permanent differences	(4.3)	8.2	1.8
Federal and state research credits—current year	(10.3)	(7.3)	(7.7)
Stock-based compensation	1.5	1.5	(9.2)
Change in valuation allowance	10.4	26.2	(0.1)
Foreign Derived Intangible Income Deduction	—	(10.2)	(8.4)
Global Intangible Low-Taxed Income	20.1	3.8	—
Change in uncertain tax positions	(11.8)	—	—
Other	7.3	8.7	0.5
(Benefit from) provision for income taxes	$ (19.0)	$ 187.2	$ 196.1

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)	**2023**	**2022**	**2021**
Beginning balance	$ 40.0	$ 17.7	$ 22.6
Increases related to current year tax positions	2.6	1.8	0.9
(Decreases) increases related to prior year tax positions	(0.1)	(0.6)	0.5
Increases due to current year acquisitions	—	27.8	—
Decreases due to settlements	(13.7)	(6.7)	—
Decreases from voluntary disclosure agreements	—	—	(6.3)
Ending balance	$ 28.8	$ 40.0	$ 17.7

As of December 31, 2023, January 1, 2023 and January 2, 2022, the Company had unrecognized tax benefits of $ 28.8 million, $ 40.0 million, and $ 17.7 million, respectively, of which $ 21.6 million, $ 28.3 million and $ 11.3 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 $ 11.7 million related to the lapse of statutes of limitations as well as 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 $ 4.0 million as of December 31, 2023 and $ 8.3 million as of January 1, 2023. The Company recognized net interest income of $ 4.3 million for fiscal year 2023 due to the reversals of prior year accrued interest; interest expense for fiscal years 2022 and 2021 was approximately $ 0.3 million and $ 0.7 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. During the fourth quarter of fiscal year 2023, the federal examination for tax years 2013 through 2014 closed with no liability due. As such, the related unrecognized tax benefits and interest were released totaling $ 19.9 million, offset by $ 5.4 million of competent authority benefits reversed. As of December 31, 2023, the remaining indemnification receivable from Johnson & Johnson totaled $ 3.0 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 2023, 2022 and 2021:

	Beginning Balance	Additions Due to Current Year Acquisitions	Additions Charged to (Benefit From) Provision for Income Taxes	Currency Translation/Other	Ending Balance
Deferred tax valuation allowance					
Fiscal year ended December 31, 2023	$ 251.3	—	10.4	13.0	$ 274.7
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

Note 7. Balance Sheet Account Details

Cash, Cash Equivalents and Restricted Cash

(In millions)	December 31, 2023	January 1, 2023
Cash and cash equivalents	$ 118.9	$ 292.9
Restricted cash included in Other assets	0.6	1.0
Cash, cash equivalents and restricted cash	$ 119.5	$ 293.9

Marketable Securities

The following table is a summary of marketable securities:

	December 31, 2023			January 1, 2023		
(In millions)	Amortized Cost	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 38.1	$ (0.1)	$ 38.0	$ 40.5	$ (0.5)	$ 40.0
Corporate asset-backed securities	8.9	—	8.9	6.7	—	6.7
U.S. government securities	—	—	—	2.0	—	2.0
Agency bonds	1.5	—	1.5	1.0	—	1.0
Sovereign government bonds	—	—	—	1.9	—	1.9
Foreign and other	—	—	—	0.5	—	0.5
Total marketable securities, current	48.5	(0.1)	48.4	52.6	(0.5)	52.1
Corporate bonds, non-current	4.5	—	4.5	13.3	(0.1)	13.2
Corporate asset-backed securities, non-current	0.9	—	0.9	7.9	(0.1)	7.8
Sovereign government bonds, non-current	2.0	—	2.0	—	—	—
Total marketable securities	$ 55.9	$ (0.1)	$ 55.8	$ 73.8	$ (0.7)	$ 73.1

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)	December 31, 2023	January 1, 2023
Accounts receivable	$ 395.1	$ 543.0
Allowance for contract rebates and discounts	(77.2)	(77.1)
Allowance for doubtful accounts	(14.6)	(12.0)
Total accounts receivable, net	$ 303.3	$ 453.9

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 $ 31.3 million and $ 40.0 million at December 31, 2023 and January 1, 2023, 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 2023, 2022 and 2021:

(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 December 31, 2023	$ 89.1	$ 493.5	$ (490.8)	$ 91.8
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

(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)	December 31, 2023	January 1, 2023
Raw materials	$ 212.7	$ 185.2
Work-in-process (materials, labor and overhead)	92.3	82.7
Finished goods (materials, labor and overhead)	318.1	295.1
Total inventories	$ 623.1	$ 563.0
Inventories	$ 577.8	$ 524.1
Other assets [(1)]	45.3	38.9
Total inventories	$ 623.1	$ 563.0

(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 consisted of the following:

(In millions)	December 31, 2023	January 1, 2023
Prepaid expenses	$ 67.0	$ 96.7
Income taxes and other tax receivables	104.7	38.6
Contract assets	46.2	49.6
Other receivables	34.2	44.3
Derivatives	6.9	22.0
Other	3.1	0.9
Total prepaid expenses and other current assets	$ 262.1	$ 252.1

Property, Plant and Equipment, Net

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

(In millions)	December 31, 2023	January 1, 2023
Equipment, furniture and fixtures	$ 595.2	$ 515.1
Building and improvements	399.7	364.7
Customer leased instruments	602.0	434.5
Land	34.7	34.5
Construction in progress	332.8	268.4
Total property, plant and equipment, gross	1,964.4	1,617.2
Less: accumulated depreciation and amortization	(520.6)	(278.2)
Total property, plant and equipment, net	$ 1,443.8	$ 1,339.0

Construction in progress reflects amounts incurred for construction or improvements of property, plant, or equipment that have not been put 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 $ 252.4 million, $ 151.1 million and $ 24.3 million for fiscal years 2023, 2022 and 2021, 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
Reallocation of goodwill [1]	$ 204.9	$ 212.6	$ (32.2)	$ (385.3)	—
Purchase accounting adjustments	(9.4)	(4.1)	(1.3)	(5.1)	(19.9)
Foreign currency translation [1]	0.7	15.3	1.1	18.0	35.1
Balance at December 31, 2023	$ 1,743.9	$ 582.4	$ 85.7	$ 80.0	$ 2,492.0

(1) During the fourth quarter of 2023, management identified an incorrect allocation of goodwill arising from the Combinations. The reallocation solely impacts the translation of foreign exchange on goodwill reflected through the cumulative translation adjustments. An out-of-period adjustment was included in fiscal year 2023 to increase goodwill and decrease Accumulated other comprehensive loss by $ 15.5 million. The adjustment was not material to the previously reported Consolidated Financial Statements of the Company.

Intangible assets consisted of the following:

		December 31, 2023			January 1, 2023		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	14.3	$ 1,000.4	$ (184.3)	$ 816.1	$ 997.6	$ (120.0)	$ 877.6
Customer relationships	19.2	2,029.0	(259.5)	1,769.5	2,023.5	(148.9)	1,874.6
License agreements	6.7	3.1	(3.1)	—	3.8	(3.7)	0.1
Patent and trademark costs	14.7	401.6	(60.1)	341.5	400.5	(32.8)	367.7
Software development costs	5.0	15.5	(8.3)	7.2	11.5	(7.7)	3.8
Total intangible assets		$ 3,449.6	$ (515.3)	$ 2,934.3	$ 3,436.9	$ (313.1)	$ 3,123.8

Amortization expense related to the capitalized software costs was $ 0.6 million, $ 0.9 million and $ 1.0 million for fiscal years 2023, 2022 and 2021, respectively. Amortization expense (including capitalized software costs) was $ 204.8 million, $ 132.5 million and $ 27.4 million for fiscal years 2023, 2022 and 2021, respectively.

The expected future annual amortization expense of the Company's finite-lived intangible assets held as of December 31, 2023 is as follows:

(In millions)	
2024	$ 202.3
2025	188.8
2026	188.1
2027	186.0
2028	180.8

Other Current Liabilities

Other current liabilities consisted of the following:

(In millions)	December 31, 2023	January 1, 2023
Accrued commissions, rebates and returns	$ 63.8	$ 57.5
Deferred revenue	36.8	76.4
Accrued interest	30.3	1.4
Operating lease liabilities	26.7	24.4
Accrued other taxes payable	17.9	9.3
Derivatives	12.1	19.7
Deferred consideration	—	39.3
Other	115.7	97.4
Total other current liabilities	$ 303.3	$ 325.4

Note 8. Borrowings

The components of borrowings were as follows:

(In millions)	December 31, 2023	January 1, 2023
Term Loan	$ 2,420.2	$ 2,646.9
Other short-term borrowings	1.6	—
Other long-term borrowings	0.4	1.2
Financing lease obligation	0.4	0.8
Unamortized deferred financing costs	(8.0)	(10.6)
Total borrowings	2,414.6	2,638.3
Less: current portion	(139.8)	(207.5)
Long-term borrowings	$ 2,274.8	$ 2,430.8

The credit agreement, dated May 27, 2022, by and among the Company, as borrower, Bank of America, N.A., as administrative agent and swing line lender, and the other lenders and L/C issuers party thereto (the “Credit Agreement”) consists of a $ 2,750.0 million Term Loan and an $ 800.0 million revolving credit facility (the “Revolving Credit Facility” and with the Term Loan, the “Financing”). 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 December 31, 2023, letters of credit issued under the Revolving Credit Facility totaled $ 12.9 million, which reduced the available amount under the Revolving Credit Facility to $ 787.1 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. As of December 31, 2023 and January 1, 2023, there were no amounts outstanding under the Revolving Credit Facility. During the year ended December 31, 2023, the Company made $ 226.7 million in payments on the Term Loan, including a voluntary prepayment of $ 20.0 million.

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 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 December 31, 2023.

The Company entered into the Credit Agreement 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.

The following table provides the detailed amounts within Interest expense, net for fiscal years 2023, 2022 and 2021:

	Fiscal Year Ended		
(In millions)	**2023**	**2022**	**2021**
Term Loan	$ 175.6	$ 73.0	$ —
Revolving Credit Facility	3.3	1.5	0.3
Amortization of deferred financing costs	3.3	2.1	0.4
Derivative instruments and other	(29.1)	0.4	5.4
Interest income	(5.5)	(1.3)	(0.3)
Interest expense, net	$ 147.6	$ 75.7	$ 5.8

The following table provides a schedule of required future repayments of all borrowings outstanding as of December 31, 2023:

(In millions)	
2024	$ 139.8
2025	137.6
2026	171.9
2027	1,973.3
2028	—
Total	$ 2,422.6

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 2023, 2022 and 2021 was $ 38.4 million, $ 26.4 million and $ 15.4 million, respectively. Variable lease cost for fiscal years 2023, 2022 and 2021 was $ 9.8 million, $ 5.6 million and $ 2.7 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)	**2023**	**2022**	**2021**
Cash paid for amounts included in the measurement of operating lease liabilities	$ 36.5	$ 25.2	$ 12.3
ROU assets obtained in exchange for new lease liabilities [(1)]	$ 17.9	$ 29.9	$ 37.3

(1) 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.

The Company leases its facilities and certain equipment. Commitments for minimum rentals under non-cancelable operating leases at the end of fiscal year 2023 were as follows:

(In millions)		
2024	$	34.6
2025		31.4
2026		27.2
2027		22.5
2028		21.9
Thereafter		100.4
Total lease payments		238.0
Less: imputed interest		(38.5)
Total		199.5
Less: current portion		(26.7)
Non-current portion	$	172.8

Weighted average remaining lease term	8.7 years
Weighted average discount rate	4 %

Undiscounted lease obligations for operating leases not yet commenced were approximately $ 3 6 million as of December 31, 2023. The obligation relates to a warehouse facility that is expected to be ready for use in 2024.

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 2023, 2022 or 2021.

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 three or four years . As of December 31, 2023, approximately 1.3 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 2023, 2022 and 2021, the Company granted approximately 0.6 million, 0.7 million and 0.1 million shares of common stock, respectively, of RSUs to certain officers and directors, which either have a time-based, three-year or four-year vesting provision or performance-based vesting provision.

During fiscal years 2023, 2022 and 2021, 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 $ 0.5 million, $ 0.6 million and $ 0.6 million for fiscal years 2023, 2022 and 2021, respectively.

Employee Deferred Bonus Compensation Program

For fiscal years 2023, 2022 and 2021, 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 of 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 December 31, 2023, 637,471 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 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 stock repurchase program was terminated. 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.

During fiscal years 2023 and 2022, 120,000 and 953,468 shares of outstanding common stock, respectively, were repurchased under the Stock Repurchase Program. As of December 31, 2023, the Company had approximately $ 218.4 million available under the Stock Repurchase Program. During fiscal year 2021, 957,239 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)	**2023**	**2022**	**2021**
Cost of sales	$ 4.3	$ 2.9	$ 2.7
Research and development	4.9	4.9	4.4
Selling, marketing and administrative	37.7	27.4	18.3
Acquisition and integration costs	16.9	30.4	—
Total stock-based compensation expense	$ 63.8	$ 65.6	$ 25.4
Income tax benefit	$ 1.7	$ 2.1	$ 0.6

The table above includes $ 12.2 million and $ 17.2 million of compensation expense related to liability-classified awards for fiscal years 2023 and 2022, respectively, which has been or is expected to be settled in cash. These awards primarily represent

the $ 7.14 per share cash settled portion of the replacement awards issued in connection with the Combinations. Cash paid to settle liability-classified awards was $ 7.3 million and $ 20.9 million for fiscal years 2023 and 2022, respectively, and was not material for fiscal year 2021.

For fiscal years 2023, 2022 and 2021, the Company recorded $ 1.5 million, $ 3.7 million and $ 3.0 million in stock-based compensation expense, respectively, associated with the deferred bonus compensation program described in "—Note 10. Stockholders' Equity."

Stock Options

A summary of the status of stock option activity for fiscal year 2023 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 1, 2023	1,656	$ 90.34		
Granted	253	88.27		
Exercised	(107)	46.42		
Cancellations	(166)	121.73		
Outstanding at December 31, 2023	1,636	$ 89.69	5.67	$ 16,774
Vested and expected to vest at December 31, 2023	1,613	$ 89.59	5.62	$ 16,774
Exercisable at December 31, 2023	1,217	$ 85.93	4.66	$ 16,774

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:

	Fiscal Year Ended		
	December 31, 2023	January 1, 2023	January 2, 2022
Risk-free interest rate	3.52 %	1.96 %	0.48 %
Expected option life (in years)	5.53	4.80	4.99
Volatility rate	57 %	57 %	54 %
Dividend rate	0 %	0 %	0 %
Weighted-average grant date fair value	$ 48.17	$ 50.62	$ 106.55

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 U.S. Treasury yield curve over the expected term of the option. The Company has never paid any cash dividends on its common stock, and does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model. The Company's estimated forfeiture rate is based on its historical experience and future expectations.

The Company's determination of fair value is affected by the Company's stock price, as well as a number of assumptions that require judgment. The total intrinsic value was $ 4.4 million, $ 13.7 million and $ 9.9 million for options exercised during fiscal years 2023, 2022, and 2021, respectively.

In January 2023, the Compensation Committee of the Board approved a modification to the vesting terms of certain stock options that were previously granted by Ortho to certain Ortho employees, such that the stock options vested on December 31, 2023. The modification resulted in an additional $ 11.1 million of stock-based compensation expense recognized during fiscal year 2023.

As of December 31, 2023, total unrecognized compensation expense related to stock options was approximately $ 14.9 million and the related weighted-average period over which it is expected to be recognized is approximately 2.0 years. The maximum contractual term of the Company's stock options is ten years .

RSUs

A summary of the status of RSU activity for fiscal year 2023 is as follows:

(In thousands, except price data)	Shares	Weighted-Average Grant Date Fair Value
Non-vested at January 1, 2023	1,032	$ 98.89
Granted	632	86.49
Vested	(422)	90.16
Forfeited	(86)	95.16
Non-vested at December 31, 2023	1,156	$ 95.56

The total amount of unrecognized compensation expense related to non-vested RSUs as of December 31, 2023 was approximately $ 68.5 million, which is expected to be recognized over a weighted-average period of approximately 2.0 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 1, 2023 and January 2, 2022 was $ 97.31 and $ 188.06 , respectively.

Note 12. Commitments and Contingencies

Purchase Obligations

The Company had $ 293.3 million of purchase obligations as of December 31, 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.

Management believes that all such current legal actions, in the aggregate, are not expected to 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 $ 21.8 million, $ 7.9 million and $ 2.0 million for fiscal years 2023, 2022 and 2021, 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:

	December 31, 2023				January 1, 2023			
(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
Marketable securities	—	55.8	—	55.8	2.0	71.1	—	73.1
Derivative assets	—	6.9	—	6.9	—	22.0	—	22.0
Total assets measured at fair value	$ —	$ 62.7	$ —	$ 62.7	$ 2.6	$ 95.2	$ —	$ 97.8
Liabilities:								
Derivative liabilities	$ —	$ 27.5	$ —	$ 27.5	$ —	$ 21.8	$ —	$ 21.8
Contingent consideration	—	—	0.1	0.1	—	—	0.1	0.1
Deferred consideration [1]	—	—	—	—	—	39.3	—	39.3
Total liabilities measured at fair value	$ —	$ 27.5	$ 0.1	$ 27.6	$ —	$ 61.1	$ 0.1	$ 61.2

(1) In connection with the acquisition of the BNP Business, the Company paid its last annual installment of $ 40.0 million during fiscal year 2023.

There were no transfers of assets or liabilities into or out of Level 3 of the fair value hierarchy during fiscal years 2023 and 2022.

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.

Financial Instruments Not Measured at Fair Value

The estimated fair value of the Company's borrowings under the Term Loan was $ 2,396.0 million at December 31, 2023, compared to the carrying amount, excluding debt issuance costs, of $ 2,420.2 million. 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. Borrowings" for additional information on the currently outstanding components of the Revolving Credit Facility and Term Loan. The Company entered into interest rate 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 its interest rate swaps 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 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 gain of $ 15.8 million as of December 31, 2023 is 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 December 31, 2023, all of which were interest rate swaps:

Notional Amount (In millions)	Description	Hedge Designation	Effective Date	Expiration Date
$ 550.0	Pay 3.765 % fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
$ 200.0	Pay 3.7725 % fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
$ 300.0	Pay 3.7675 % fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
$ 400.0	Pay 3.7575 % fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027
$ 350.0	Pay 3.7725 % fixed, receive floating rate (1-month USD-SOFR)	Designated cash flow hedge	December 30, 2022	May 27, 2027

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, Colombian Peso, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Philippine Peso, South Korean Won, Swiss Franc, Danish Krone, Czech Koruna and 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 $ 6.7 million as of December 31, 2023 is expected to be reclassified from OCI 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 December 31, 2023:

Description	Notional Amount (In millions)	Hedge Designation
Foreign currency forward contracts	$ 448.8	Cash Flow Hedge
Foreign currency forward contracts	803.4	Non-designated

The following table summarizes pre-tax gains and losses from designated derivative and non-derivative instruments within AOCI for fiscal years ended December 31, 2023 and January 1, 2023:

	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
Fiscal Year Ended December 31, 2023			
Foreign currency forward contracts (sales)	$ 7.0	Total revenues	$ 4.3
Foreign currency forward contracts (purchases)	(2.5)	Cost of sales, excluding amortization of intangibles	1.9
Interest rate derivatives	(13.4)	Interest expense, net	(30.1)
Fiscal Year Ended January 1, 2023			
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 year 2021 were not material.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. In fiscal year 2023, the Company entered into forward contracts that are designated as hedges of the net investment in a foreign operations. The unrealized gains or losses on these contracts are recorded in translation adjustment within OCI, and remain in AOCI until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in OCI. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument.

The effect of the Company's net investment hedges on OCI and the Consolidated Statements of (Loss) Income are shown below:

	Amount of Pre-tax (Gain) Loss Recognized in OCI	Amount of Pre-tax (Gain) Loss Recognized in Other Expense (Income), Net for Amounts Excluded from Effectiveness Testing
Fiscal Year Ended December 31, 2023		
Net Investment Hedging Relationships		
Foreign exchange contracts	$ 8.5	$ (1.0)

Fair value (gains) and losses on foreign currency forward contracts, as determined using Level 2 inputs, that do not qualify for hedge accounting treatment are recorded in Other expense (income), net and were not material for fiscal years 2023, 2022 and 2021.

Fair value gains on interest rate derivatives, as determined using Level 2 inputs, that do not qualify for hedge accounting treatment are recorded in Other expense (income), net and were $ 3.4 million for fiscal year 2022 and were immaterial for fiscal year 2021. There were no fair value gains and losses on interest rate derivatives that do not qualify for hedge accounting treatment for fiscal year 2023.

The following table summarizes the fair value of designated and non-designated hedging instruments recognized within the Consolidated Balance Sheets as of December 31, 2023 and January 1, 2023:

(In millions)	December 31, 2023	January 1, 2023
Designated cash flow hedges		
Interest rate derivatives:		
Prepaid expenses and other current assets	$ 0.2	$ 15.9
Other liabilities	6.9	2.1
Foreign currency forward contracts:		
Prepaid expenses and other current assets	3.2	4.6
Other current liabilities	9.4	14.3
Other liabilities	8.5	—
Non-designated hedging instruments		
Foreign currency forward contracts:		
Prepaid expenses and other current assets	3.5	1.5
Other current liabilities	2.7	5.4

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 dates used to determine the defined benefit and other post-employment benefit obligations were December 31, 2023 and January 1, 2023. The following tables set forth the changes to the projected benefit obligations ("PBO") and plan assets:

	Fiscal Year Ended	
(In millions)	December 31, 2023	January 1, 2023
Defined Benefit Plans		
Change in benefit obligation:		
Projected benefit obligation at beginning of year	$ 33.9	$ —
Service cost	2.0	1.2
Interest cost	1.0	0.4
Benefits paid	(0.2)	(0.3)
Actuarial loss (gain)	2.8	(0.6)
Assumed obligation from the Combinations	—	33.3
Settlements	(2.4)	(0.2)
Foreign currency exchange rate changes	(0.2)	0.1
Projected benefit obligation at end of year	$ 36.9	$ 33.9
Change in plan assets:		
Fair value of plan assets at beginning of year	$ 20.6	$ —
Actual return on plan assets	1.1	(0.5)
Employer contributions	2.1	1.6
Benefits paid	(0.2)	(0.3)
Transfers in from the Combinations	—	20.1
Settlements	(2.4)	(0.2)
Foreign currency exchange rate changes	(0.8)	(0.1)
Fair value of plan assets at end of year	$ 20.4	$ 20.6
Funded status at end of year	$ (16.5)	$ (13.3)
Amounts recognized on the consolidated balance sheets:		
Other assets	$ 0.7	$ 0.4
Other current liabilities	(0.4)	(0.3)
Other liabilities	(16.8)	(13.4)
Net amount recognized	$ (16.5)	$ (13.3)

(In millions)	Fiscal Year Ended December 31, 2023	Fiscal Year Ended January 1, 2023
Other Post-employment Benefits		
Change in benefit obligation:		
Projected benefit obligation at beginning of year	$ 18.6	$ 18.9
Service cost	0.4	0.3
Interest cost	0.9	0.4
Benefits paid	(1.1)	(0.7)
Actuarial gain	(0.3)	(0.7)
Assumed obligation from the Combinations	—	0.4
Projected benefit obligation at end of year	$ 18.5	$ 18.6
Amounts recognized on the consolidated balance sheets:		
Other current liabilities	$ (3.9)	$ (3.5)
Other liabilities	(14.6)	(15.1)
Net amount recognized	$ (18.5)	$ (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 December 31, 2023 and January 1, 2023. Further, the table reflects the aggregate PBO, ABO and fair value of plan assets for defined benefit plans with PBO in excess of plan assets and for defined benefit plans with ABO in excess of plan assets.

(In millions)	December 31, 2023	January 1, 2023
ABO	$ 29.3	$ 27.1
Plans with PBO in excess of plan assets		
PBO	$ 22.2	$ 18.3
Fair value of plan assets	5.7	5.1
Plans with ABO in excess of plan assets		
PBO	$ 20.4	$ 17.0
ABO	17.6	14.3
Fair value of plan assets	4.0	3.8

The pretax amounts that are not yet reflected in the net periodic benefit cost and are included in AOCI as of December 31, 2023 and January 1, 2023 include the following:

(In millions)	Fiscal Year Ended December 31, 2023	Fiscal Year Ended January 1, 2023
Defined Benefit Plans		
Accumulated net actuarial losses	$ (2.3)	$ (0.2)
Accumulated prior service credit	$ 0.1	$ —
Other Post-employment Benefits		
Accumulated net actuarial gains	$ 0.9	$ 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 $ 2.5 million and $ 1.4 million for the fiscal years ended December 31, 2023 and January 1, 2023, respectively, and was primarily related to service cost. Changes in plan assets and benefit obligations recognized in other comprehensive income were $ 2.1 million and $ 0.1 million for the fiscal years ended December 31, 2023 and January 1, 2023, respectively.

Net periodic benefit cost for the Company's other post-employment benefit plans was $ 1.3 million and $ 0.7 million for the fiscal years ended December 31, 2023 and January 1, 2023, respectively, and was primarily related to interest cost. Changes in benefit obligations recognized in other comprehensive income were not material for fiscal years 2023 and 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 (Loss) Income.

Assumptions and Sensitivities

The following assumptions were used to measure the fair value of the benefit obligations and associated plan assets for the periods below:

	December 31, 2023	January 1, 2023
Defined Benefit Plans		
Weighted average discount rate	3.3 %	3.1 %
Weighted average rate of compensation increases	3.2 %	3.0 %
Other Post-employment Benefit Plans		
Weighted average discount rate	4.8 %	5.5 %

The critical assumptions used in determining the net periodic benefit cost for fiscal years 2023 and 2022 are as follows:

	December 31, 2023	January 1, 2023
Defined Benefit Plans		
Weighted average discount rate	3.1 %	2.2 %
Weighted average expected rate of compensation increases	3.0 %	2.6 %
Weighted average expected return on plan assets	2.5 %	2.5 %
Other Post-employment Benefit Plans		
Weighted average discount rate	5.5 %	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:

	December 31, 2023
Health care cost trend rate assumed for next year - Pre-65	6.12 %
Health care cost trend rate assumed for next year - Post-65	5.87 %
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 December 31, 2023, the Company expects to contribute $ 1.9 million to defined benefit plans in fiscal year 2024.

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
2024	$ 1.9	$ 3.9
2025	2.1	3.5
2026	1.7	2.7
2027	3.5	2.1
2028	2.0	1.8
2029-2033	13.9	5.4

Plan Assets

The tables below present the fair value of the defined benefit plans by level within the fair value hierarchy, as described in "—Note 1. Basis of Presentation and Summary of Significant Accounting Policies" at December 31, 2023 and January 1, 2023.

	Fair Value Measurements at December 31, 2023			
(In millions)	Total	Level 1	Level 2	Level 3
U.S. equity securities	$ 2.1	$ 2.1	$ —	$ —
Japan equity securities	3.6	3.6	—	—
Other international equity securities	1.5	1.5	—	—
U.S. government bonds	0.4	0.4	—	—
Japan government bonds	0.5	0.5	—	—
Other international government bonds	1.5	1.5	—	—
Cash and cash equivalents	5.1	5.1	—	—
Insurance contracts	5.7	—	—	5.7
Total	$ 20.4	$ 14.7	$ —	$ 5.7

(In millions)	Fair Value Measurements at January 1, 2023			
	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, Korea and Philippines. The Japanese and Philippines 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 defined benefit 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 defined benefit 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 40 % for debt securities, 57 % for equity securities and 2 % for other assets.

The table below presents a roll-forward of activity for the Level 3 assets for fiscal years 2023 and 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
Transfers out	(1.0)
Net purchases and settlements	0.6
Balance at December 31, 2023	$ 5.7

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 $ 18.6 million, $ 15.1 million and $ 3.8 million for fiscal years ended 2023, 2022 and 2021, respectively, which are recognized as expense as incurred in the Consolidated Statements of (Loss) 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, Quotient's next generation product in immunohematology, a transfusion diagnostic patient immunohematology microarray intended for use with Quotient's MosaiQ® instruments. Under the Letter Agreement, the Company was required to make certain milestone payments to Quotient as specified milestones and benchmarks were achieved. Quotient subsequently revised its business strategy to pause development and commercialization of its MosaiQ testing solutions in immunohematology and infectious disease immunoassay screening. 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”). Following the completion of the Bankruptcy Proceeding, the Company’s equity interests in Quotient were canceled for no consideration. Quotient is no longer considered a related party of the Company.

Note 17. Accumulated Other Comprehensive Loss

The following table summarizes the changes in balance of AOCI by component:

(In millions)	Pension and Other Post-employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Unrealized Foreign Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income
Balance at January 2, 2022	$ —	$ —	$ (0.1)	$ 0.5	$ 0.4
Current period deferrals [1]	0.7	6.7	(0.4)	(69.8)	(62.8)
Amounts reclassified to Net (loss) income	—	(5.2)	—	—	(5.2)
Net change	0.7	1.5	(0.4)	(69.8)	(68.0)
Balance at January 1, 2023	$ 0.7	$ 1.5	$ (0.5)	$ (69.3)	$ (67.6)
Current period deferrals [1]	(2.0)	12.6	0.5	50.4	61.5
Amounts reclassified to Net (loss) income	—	(23.9)	—	—	(23.9)
Net change	(2.0)	(11.3)	0.5	50.4	37.6
Balance at December 31, 2023	$ (1.3)	$ (9.8)	$ —	$ (18.9)	$ (30.0)

(1) Includes tax impact of $ 3.7 million and $ 0.1 million related to cash flow hedges for fiscal years 2023 and 2022, respectively.

Amounts related to fiscal year 2021 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), as of the end of the fiscal year. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 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: There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 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 December 31, 2023.

The effectiveness of our internal control over financial reporting as of December 31, 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 December 31, 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 December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and January 1, 2023, the related consolidated statements of (loss) income, comprehensive income, stockholders' equity and cash flows, for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 29, 2024 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 29, 2024

Item 9B. Other Information

(a) None.

(b) During the last fiscal quarter, no director or officer (as defined in Exchange Act Rule 16a-1(f)) adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement.

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 2024 definitive proxy statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023 (the "2024 Proxy Statement"), including under the headings "Proposal One - Election of Directors Proposal," "Corporate Governance," "Executive Officers" and "Delinquent Section 16(a) Reports."

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our 2024 Proxy Statement, including under the headings "Director Compensation," "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 2024 Proxy Statement, including under the headings "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" and "Securities Authorized for Issuance under Equity Compensation Plans."

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

The information required by this item is incorporated herein by reference to our 2024 Proxy Statement, including under the headings "Director Independence," "Review and Approval of Related Party Transactions" and "Related Party Transactions."

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our 2024 Proxy Statement, including under the headings "Independent Registered Public Accounting Firm" and "Policy on Audit Committee Pre-approval of Audit and Permissible Non-audit Services."

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 the Annual Report by Exchange Act 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. 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 (incorporated by reference to Exhibit 3.3 to the Registrant's Form 10-K for the fiscal year ended January 1, 2023 filed on February 23, 2023)
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 (incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K for the fiscal year ended January 1, 2023, filed on February 23, 2023)
10.1	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. on January 31, 2022)

Exhibit Number	Description
10.2+	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)
10.3	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)
10.4(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)
10.5(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)
10.6(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)
10.7(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)
10.8(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)
10.9(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)
10.10(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)
10.11(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)
10.12(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 on January 20, 2009)
10.13(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 on June 6, 2008)
10.14(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 on January 18, 2022)
10.15(1)	Form of Integration and Retention Bonus Letter (incorporated by reference to Exhibit 10.4 to the Form 8-K filed by Quidel Corporation on February 4, 2022)
10.16(1)	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.10 to the Registrant's Form 8-K filed on May 27, 2022)
10.17(1)	Form of Severance and Change in Control Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 1, 2023)
10.18(1)	Amended and Restated Individual Retirement Program for Werner Kroll, effective as of April 4, 2023 (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended April 2, 2023 filed on May 4, 2023)
10.19(1)*	QuidelOrtho Board Deferred Compensation Plan
10.20(1)*	QuidelOrtho Employee Deferred Compensation Plan
10.21	Summers Ridge Lease (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by Quidel Corporation on January 9, 2018)
10.22	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

Exhibit Number	Description
31.1*	Certification by Principal Executive Officer of QuidelOrtho Corporation pursuant to Rules 13a-14 (a) and 15d-14(a), 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 (a) and 15d-14(a), 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
97.1*	QuidelOrtho Clawback Policy
101*	The following financial statements from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of (Loss) Income, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104	The cover page from the Registrant's Annual Report on Form 10-K for the year ended December 31, 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 Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

QUIDELORTHO CORPORATION

By /s/ MICHAEL S. ISKRA

Michael S. Iskra
Interim Chief Executive Officer
(Principal Executive Officer)

Date: February 29, 2024

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/ MICHAEL S. ISKRA Michael S. Iskra	Interim Chief Executive Officer (Principal Executive Officer)	February 29, 2024
/s/ JOSEPH M. BUSKY Joseph M. Busky	Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2024
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 29, 2024
/s/ EVELYN S. DILSAVER Evelyn S. Dilsaver	Director	February 29, 2024
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 29, 2024
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 29, 2024
/s/ JAMES R. PRUTOW James R. Prutow	Director	February 29, 2024
/s/ ANN D. RHOADS Ann D. Rhoads	Director	February 29, 2024
/s/ ROBERT R. SCHMIDT Robert R. Schmidt	Director	February 29, 2024
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 29, 2024
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 29, 2024
/s/ JOSEPH D. WILKINS JR. Joseph D. Wilkins Jr.	Director	February 29, 2024

QUIDELORTHO CORPORATION
BOARD DEFERRED COMPENSATION PLAN

In December 2010, the board of directors of Quidel Corporation ("**Quidel**") adopted the Board Deferred Compensation Program that began in 2011 (the "**Prior Program**"). In May 2022, in connection with the business combination (the "**Combinations**") among Quidel, Ortho Clinical Diagnostics Holdings plc ("**Ortho**") and QuidelOrtho Corporation, a Delaware corporation (the "**Company**"), each of Quidel and Ortho became a wholly owned subsidiary of the Company, and the Company continued the Prior Program following the Combinations. For purposes of regulatory updates and administrative ease, the Company hereby amends and restates the Prior Program and implements this QuidelOrtho Corporation Board Deferred Compensation Plan (this "**Plan**"), effective as of November 27, 2023 (the "**Effective Date**"). This Plan is intended to be, and shall be administered as, an unfunded plan maintained for the purpose of providing deferred compensation for non-employee directors of the Board. This Plan is also intended to comply with the requirements of Section 409A (as defined below).

1. **Purpose**. The purpose of this Plan is to provide non-employee directors of the Board with the opportunity to elect to defer certain cash compensation paid by the Company into a grant of RSUs.

2. **Definitions**. For purposes of this Plan:

(a) **"Account"** shall mean the separate account maintained on the books of the Company for each Participant pursuant to Section 5. RSUs shall only be credited to a Participant's Account once vested.

(b) **"Board"** shall mean the Board of Directors of the Company.

(c) **"Code"** shall mean the Internal Revenue Code of 1986, as amended.

(d) **"Committee"** shall mean the Compensation Committee of the Board, or a subcommittee thereof, or such other committee designated by the Board to administer this Plan.

(e) **"Covered Fees"** shall mean a Participant's (i) annual cash retainer fee and (ii) cash compensation for service as a chairperson of the Board or any of its standing committees.

(f) **"Eligible Director"** shall mean a non-employee director of the Board. An individual will cease to be an Eligible Director on the earliest of (i) the date the individual ceases to serve on the Board, or (ii) the date this Plan is terminated.

(g) **"Fair Market Value"** means as of any date the closing price of the Shares as reported on the Nasdaq Stock Market for that date or, if no closing price is reported for that date, the closing price on the next preceding date for which a closing price is reported, unless otherwise determined by the Committee.

(h) **"Grant Date"** shall mean, for both Converted RSUs and Premium RSUs (each as defined below), the date that is six (6) business days following the first day of the applicable Covered Period (as defined below).

(i) **"Participant"** shall mean an Eligible Director who makes a deferral election under Section 4 of this Plan.

(j) **"Plan"** shall mean the QuidelOrtho Corporation Board Deferred Compensation Plan, as set forth herein and as may be amended from time to time.

(k) **"RSUs"** shall mean restricted stock units granted to the Participant under the Stock Plan.

(l) **"Section 409A"** shall mean Section 409A of the Code.

(m) **"Separation from Service"** shall mean a "separation from service" from the Company, within the meaning of Section 409A and the regulations promulgated thereunder.

(n) **"Shares"** shall mean shares of the Company's common stock, par value $0.001 per share, and all rights appurtenant thereto.

(o) **"Stock Plan"** shall mean the QuidelOrtho Corporation Amended and Restated 2018 Equity Incentive Plan, as amended from time to time, or any successor equity plan adopted by the Company.

3. **Administration**. This Plan shall be administered by the Committee. The Committee shall, subject to the terms of this Plan, interpret this Plan and the application thereof and establish, amend and revoke interpretations, rules and conditions as it deems necessary or desirable for the administration of this Plan. All such interpretations, rules and conditions shall be final, binding and conclusive upon the Participants and all other persons having or claiming any right or interest in this Plan, the Converted RSUs or the Premium RSUs. No member of the Board or Committee, and no officer of the Company to whom the Committee delegates any of its power and authority hereunder, shall be liable for any act, omission, interpretation, construction or determination made in connection with this Plan in good faith.

4. **Covered Fees Deferrals**.

(a) **Eligibility**. Each Eligible Director shall be eligible to participate in this Plan and to make the elections provided under Sections 4(b) and 4(c). Any amounts deferred in accordance with this Section 4 shall be credited to the Participant's Account in the form of RSUs as set forth in Section 5(a).

(b) **Covered Fees Deferral Election**. Prior to the commencement of each fiscal year, an Eligible Director may elect to defer 50% or 100% of the Covered Fees he or she will earn during the period beginning on the date of the Company's annual meeting of stockholders in that fiscal year and ending on the date of the Company's annual meeting of stockholders in the following fiscal year (the "**Covered Period**") by completing and submitting a written election form, in the form approved by the Committee, to the People and Culture Department. After the date specified in the election form, Participants' elections will be irrevocable. If an Eligible Director does not make a timely election for an upcoming Covered Period, no deferral of the Covered Fees will be made on behalf of that Eligible Director for that upcoming Covered Period.

(c) **Deferral Period Election**. If an Eligible Director elects to defer his or her Covered Fees in accordance with Section 4(b), to be a valid election, the Eligible Director must also elect one of the following deferral periods (the "**Deferral Period**") in the written election form:

(i) One (1) year from the applicable Grant Date;

(ii) Two (2) years from the applicable Grant Date; or

(iii) Four (4) years from the applicable Grant Date.

(d) **Grant and Vesting of Converted RSUs**. With respect to the deferred portion of a Participant's Covered Fees, in lieu of cash, on the Grant Date, the Participant will receive a grant of RSUs under the Stock Plan that will vest quarterly in equal installments on the same date the Company makes (or otherwise would make, if all directors elect to participate 100%) quarterly cash payments of the Covered Fees to non-Participants, subject to the Participant's continued service through each vesting date (the "**Converted RSUs**"). Notwithstanding the foregoing vesting requirement, the vesting of Converted RSUs shall accelerate in full upon a Change in Control (as defined in the Stock Plan), subject to the Participant's continued service through to the date of such Change in Control. The number of Converted RSUs to be granted in respect of Covered Fees shall be equal to the result of dividing the installment amount deferred by the Fair Market Value of one Share on the applicable Grant Date (rounded down to the nearest whole number).

(e) **Grant and Vesting of Premium RSUs**. In addition, on the Grant Date, a Participant will also receive a grant of additional RSUs under the Stock Plan that will vest in full on the first anniversary of the applicable Grant Date, or such other date as specified in the applicable election form and grant notice evidencing the grant of such RSUs, subject to the Participant's continued service through such date (the "**Premium RSUs**"). Notwithstanding the foregoing vesting requirement, the vesting of Premium RSUs shall accelerate in full upon a Change in Control (as defined in the Stock Plan), subject to the Participant's continued service through to the date of such Change in Control. The number of Premium RSUs to be granted shall be determined based on the Deferral Period elected by the Participant as follows: (i) if one (1) year from the Grant Date, a premium of 10% on the amount deferred of the Covered Fees; (ii) if two (2) years from the Grant Date, a premium of 20% on the amount deferred of the Covered Fees; or (iii) if four (4) years from the Grant Date, a premium of 30% on the amount deferred of the Covered Fees. The number of Premium RSUs to be granted shall be equal to the result of dividing such premium amount by the Fair Market Value of one Share on the applicable Grant Date (rounded down to the nearest whole number).

5. **Account**.

(a) **Crediting to Participants' Accounts**. Converted RSUs and Premium RSUs will be credited to the Participant's Account as of the date the Converted RSUs and Premium RSUs are vested pursuant to Sections 4(d) and 4(e), respectively (i.e., for Converted RSUs, quarterly in equal installments on the same date the Company makes quarterly cash payments of the Covered Fees to non-Participants; and for Premium RSUs, upon the first anniversary of the applicable Grant Date, or such other date as specified in the applicable election form and grant notice evidencing the grant of such RSUs). Any Converted RSUs or Premium RSUs that do not become vested shall be forfeited.

(b) **Cash Dividends**. Whenever any cash dividends are declared on the Shares, the Company will credit the Account of each Participant on the date such dividend is paid with a number of additional RSUs equal to the result of dividing (i) the product of (x) the total number of RSUs credited to the Participant's Account on the record date for such dividend and (y) the per Share amount of such dividend by (ii) the Fair Market Value of one Share on the date such dividend is paid by the Company to the holders of Shares.

(c) **Capitalization Adjustments**. In the event of (i) any change in the Shares through a merger, consolidation, reorganization, recapitalization or otherwise, (ii) a stock dividend, or (iii) a stock split, combination or other changes to the Shares, all as described in Section 3.4 of the Stock Plan, the RSUs granted to each Participant shall be increased or decreased proportionately in accordance with Section 3.4 of the Stock Plan.

6. **Issuance of Shares**. Converted RSUs and Premium RSUs shall be granted under the Stock Plan and shall be considered "Restricted Stock Units" granted pursuant to Section 6.10 of the Stock Plan. Issuance of the Shares underlying the RSUs credited to the Participant's Account shall be made to the Participant (or, in the event of the Participant's death, to the Participant's beneficiary, as provided in Section 8) upon the earlier to occur of (i) the end of the Deferral Period elected by the Participant, (ii) a Change in Control or (iii) a Participant's Separation from Service. For avoidance of doubt, Converted RSUs and Premium RSUs will only be credited to a Participant's Account upon vesting.

(a) **Distribution upon Death**. If a Participant incurs a Separation from Service due to death or his or her death occurs after Separation from Service but before issuance to him or her of the Shares underlying the RSUs credited to his or her Account, then all or the remaining RSUs credited to his or her Account shall be released and the Shares underlying these RSUs shall be issued to such Participant's beneficiaries within 30 days following the date of death.

7. **Corporate Transaction**. In the event of a Change in Control that constitutes a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the Company's assets under Section 409A, the Shares underlying the RSUs credited to the Account of each Participant shall be converted into shares of the successor entity in accordance with the terms of the Stock Plan or, if elected by the Board, shall be paid to the Participant in a lump sum in cash.

8. **Beneficiary Designation**. Each Participant shall have the right, at any time, to designate any person or persons as his beneficiary or beneficiaries to whom issuance of Shares under this Plan shall be made in the event of his or her death. Any beneficiary designation may be made or changed by a Participant by a written instrument, in such form prescribed by the Company, which is filed with the Company prior to the Participant's death. If a Participant fails to designate a beneficiary, or if all designated beneficiaries predecease the Participant, the Shares underlying the RSUs credited to the Participant's Account shall be issued to the Participant's estate.

9. **Amendment and Termination**. The Committee may amend or terminate this Plan at any time in whole or in part; provided, however, that no amendment or termination shall reduce the RSUs credited to a Participant's Account (except in the case of any adjustments in accordance with Section 3.4 of the Stock Plan) or adversely affect the rights of a Participant to such RSUs, without the consent of the Participant (or the Participant's beneficiary in the event of the Participant's death). Notwithstanding the foregoing, this Plan may be amended at any time, without the consent of any Participant (or beneficiary) if necessary or desirable to comply with the requirements, or avoid the application, of Section 409A.

10. **General Provisions**.

(a) **Unfunded Plan**. The Company's obligation to grant RSUs and issue Shares under this Plan shall be contractual only and all such grants and issuances hereunder shall be made by the Company from its general assets at the time and in the manner provided for in this Plan. No funds, securities or other property of any nature shall be segregated or earmarked for any current or former Participant, beneficiary or other person, and his or her sole right is as a general creditor of the Company with an unsecured claim against its general assets.

(b) **Non-Alienation of Benefits**. Neither a Participant nor any other person shall have any rights to sell, assign, transfer, pledge, anticipate, or otherwise encumber the RSUs granted under this Plan to the Participant or any other person. Any attempted sale, assignment, transfer or pledge shall be null and void and without any legal effect. No part of the RSUs granted under this Plan shall be subject to seizure or sequestration for the payment of any debts, judgments, alimony or separate maintenance owed by a Participant or any other person, nor be transferable by operation of law in the event of a Participant's or any other person's bankruptcy or insolvency.

(c) **Section 409A**. Notwithstanding any provision of this Plan to the contrary, this Plan will be construed, administered or deemed amended as necessary to comply with the requirements of Section 409A to avoid taxation under Section 409A to the extent Section 409A applies to this Plan. Each benefit hereunder shall constitute a "separately identified" amount within the meaning of Treasury Regulation §1.409-2(b)(2). The Committee, in its sole discretion shall determine the requirements of Section 409A that are applicable to this Plan and shall interpret the terms of this Plan in a manner consistent therewith. Under no circumstances, however, shall the Company or any affiliate or any of its or their employees, officers, directors, service providers or agents have any liability to any person for any taxes, penalties or interest due on the Shares issued or issuable under this Plan, including any taxes, penalties or interest imposed under Section 409A.

(d) **No Stockholder Rights**. Neither the Participant nor any other person shall have any rights as a stockholder of the Company with respect to the RSUs credited to the Participant's Account until the Shares underlying the RSUs are issued to the Participant (or the beneficiary of the Participant).

(e) **Severability**. If any provision of this Plan shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining provisions of this Plan, and this Plan shall be enforced as if the invalid provisions had never been set forth herein.

(f) **Successors in Interest**. The obligation of the Company under this Plan shall be binding upon any successor(s) of the Company, whether by merger, consolidation, sale of assets or otherwise, and for this purpose reference herein to the Company shall be deemed to include any such successor(s).

(g) **Governing Law; Interpretation**. To the extent not governed by Federal law, this Plan shall be construed and enforced in accordance with, and governed by, the laws of the State of Delaware, without giving effect to principles of conflict of laws.

QUIDELORTHO CORPORATION
EMPLOYEE DEFERRED COMPENSATION PLAN

In December 2010, the board of directors of Quidel Corporation ("**Quidel**") adopted the Employee Deferred Compensation Program that began in 2011 (the "**Prior Program**"). In May 2022, in connection with the business combination (the "**Combinations**") among Quidel, Ortho Clinical Diagnostics Holdings plc ("**Ortho**") and QuidelOrtho Corporation, a Delaware corporation (the "**Company**"), each of Quidel and Ortho became a wholly owned subsidiary of the Company, and the Company continued the Prior Program following the Combinations. For purposes of regulatory updates and administrative ease, the Company hereby amends and restates the Prior Program and implements this QuidelOrtho Corporation Employee Deferred Compensation Plan (this "**Plan**"), effective as of November 27, 2023 (the "**Effective Date**"). This Plan is intended to be, and shall be administered as, an unfunded plan maintained for the purpose of providing deferred compensation for a select group of management or highly compensated employees within the meaning of ERISA (as defined below). This Plan is also intended to comply with the requirements of Section 409A (as defined below).

1. **Purpose**. The purpose of this Plan is to provide certain employees of the Company with the opportunity to elect to defer certain cash compensation paid by the Company into a grant of RSUs.

2. **Definitions**. For purposes of this Plan:

(a) **"Account"** shall mean the separate account maintained on the books of the Company for each Participant pursuant to Section 5. RSUs shall only be credited to a Participant's Account once vested.

(b) **"Board"** shall mean the Board of Directors of the Company.

(c) **"Bonus"** shall mean a Participant's earned annual cash bonus under the Company's Global Bonus Plan, or any annual cash bonus under a successor program of the Company.

(d) **"Code"** shall mean the Internal Revenue Code of 1986, as amended.

(e) **"Committee"** shall mean the Compensation Committee of the Board, or a subcommittee thereof, or such other committee designated by the Board to administer this Plan.

(f) **"Eligible Employee"** shall mean a U.S. employee of the Company or of a Subsidiary who is a member of a select group of management or highly compensated employees within the meaning of ERISA, and has been notified in writing by the Company of eligibility for Plan participation. Unless the Committee determines otherwise, Eligible Employees shall be limited to those U.S. employees of the Company or of a Subsidiary with the job code title of Director or a more senior title. An individual will cease to be an Eligible Employee on the earliest of (i) the date the individual ceases to be employed by the Company and all Subsidiaries, (ii) the date this Plan is terminated, or (iii) the date the Company's Chief Executive Officer, in his/her discretion, determines that the individual is no longer an Eligible Employee. In addition to the foregoing, the Committee may, in its discretion, deny eligibility to any employee or group of employees who may previously have been Eligible Employees.

(g) **"ERISA"** shall mean the Employee Retirement Income Security Act of 1974, as amended.

(h) **"Fair Market Value"** means as of any date the closing price of the Shares as reported on the Nasdaq Stock Market for that date or, if no closing price is reported for that date, the closing price on the next preceding date for which a closing price is reported, unless otherwise determined by the Committee.

(i) **"Identification Date"** shall mean each December 31.

(j) **"Participant"** shall mean an Eligible Employee who makes a deferral election under Section 4 of this Plan.

(k) **"Plan"** shall mean the QuidelOrtho Corporation Employee Deferred Compensation Plan, as set forth herein and as may be amended from time to time.

(l) **"RSUs"** shall mean restricted stock units granted to the Participant under the Stock Plan.

(m) **"Section 409A"** shall mean Section 409A of the Code.

(n) **"Separation from Service"** shall mean a "separation from service" from the Company, within the meaning of Section 409A and the regulations promulgated thereunder.

(o) **"Shares"** shall mean shares of the Company's common stock, par value $0.001 per share, and all rights appurtenant thereto.

(p) **"Specified Employee"** shall mean a Participant who, on an Identification Date, is a "Specified Employee" as such term is defined in Section 409A. As of the Effective Date, a Specified Employee is:

(i) An officer of the Company having annual compensation greater than the compensation limit in Section 416(i)(1)(A)(i) of the Code, provided that no more than 50 officers of the Company shall be determined to be Specified Employees as of any Identification Date;

(ii) A 5% owner of the Company regardless of compensation; or

(iii) A 1% owner of the Company having annual compensation from the Company of more than $150,000.

If a Participant is identified as a Specified Employee on an Identification Date, then such Participant shall be considered a Specified Employee for purposes of this Plan during the period beginning on the first April 1 following the Identification Date and ending on the next March 31.

(q) **"Stock Plan"** shall mean the QuidelOrtho Corporation Amended and Restated 2018 Equity Incentive Plan, as amended from time to time, or any successor equity plan adopted by the Company.

(r) **"Subsidiary"** shall mean any entity (other than the Company) in an unbroken chain of entities beginning with the Company, provided each entity (other than the last entity) in the unbroken chain owns, at the time of the determination, stock possessing 50% or more of the total combined voting power of all classes of equity in one of the other entities in such chain.

3. **Administration**. This Plan shall be administered by the Committee. The Committee shall, subject to the terms of this Plan, interpret this Plan and the application thereof and establish, amend and revoke interpretations, rules and conditions as it deems necessary or desirable for the administration of this Plan. All such interpretations, rules and conditions shall be final, binding and conclusive upon the Participants and all other persons having or claiming any right or interest in this Plan, the Converted RSUs or the Premium RSUs (each as defined below). No member of the Board or Committee, and no officer of the Company to whom the Committee delegates any of its power and authority hereunder, shall be liable for any act, omission, interpretation, construction or determination made in connection with this Plan in good faith.

4. **Bonus Deferrals**.

(a) **Eligibility**. Each Eligible Employee shall be eligible to participate in this Plan and to make the elections provided under Sections 4(b) and 4(c). Any amounts deferred in accordance with this Section 4 shall be credited to the Participant's Account in the form of RSUs as set forth in Sections 5(a) and 5(b).

(b) **Bonus Deferral Election**. Prior to the commencement of each fiscal year, an Eligible Employee may elect to defer 50% or 100% of the Bonus he or she will earn during that fiscal year (net of any applicable withholding taxes or other authorized deductions to the extent required so that such applicable withholding taxes or other authorized deductions shall be satisfied from the Bonus) by completing and submitting a written election form, in the form approved by the Committee, to the People and Culture Department. With respect to a Bonus that qualifies as performance-based compensation under Section 409A of the Code, such election must be made no less than 6 months before the end of the applicable Bonus performance period. After the date specified in the election form, Participants' elections will be irrevocable. If an Eligible Employee does not make a timely election for an upcoming fiscal year, no Bonus deferral will be made on behalf of that Eligible Employee for that upcoming fiscal year.

(c) **Deferral Period Election**. If an Eligible Employee elects to defer his or her Bonus in accordance with Section 4(b), to be a valid election, the Eligible Employee must also elect one of the following deferral periods (the "**Deferral Period**") in the written election form:

(i) One (1) year from the applicable Grant Date (as defined below);

(ii) Two (2) years from the applicable Grant Date; or

(iii) Four (4) years from the applicable Grant Date.

(d) **Grant and Vesting of Converted RSUs**. With respect to the deferred portion of a Participant's Bonus, in lieu of cash, on the Grant Date, the Participant will receive a grant of RSUs under the Stock Plan that will vest in full on the Grant Date (the "**Converted RSUs**"). The number of Converted RSUs to be granted in respect of a Bonus shall be equal to the result of dividing the amount deferred by the Fair Market Value of one Share on the applicable Grant Date (rounded down to the nearest whole number).

(e) **Grant and Vesting of Premium RSUs**. In addition, on the Grant Date, a Participant will also receive a grant of additional RSUs under the Stock Plan that will vest in full on the first anniversary of the applicable Grant Date, or such other date as specified in the applicable election form and grant notice evidencing the grant of such RSUs, subject to the Participant's continued service through such date (the "**Premium RSUs**"). Notwithstanding the foregoing vesting requirement, the vesting of Premium RSUs shall accelerate in full upon a Change in Control (as defined in the Stock Plan), subject to the Participant's continued service through to the date of such Change in Control. The number of Premium RSUs to be granted shall be determined based on the Deferral Period elected by the Participant as follows: (i) if one (1) year from the Grant Date, a premium of 10% on the amount deferred of the Bonus; (ii) if two (2) years from the Grant Date, a premium of 20% on the amount deferred of the Bonus; or (iii) if four (4) years from the Grant Date, a premium of 30% on the amount deferred of the Bonus. The number of Premium RSUs to be granted shall be equal to the result of dividing such premium amount by the Fair Market Value of one Share on the applicable Grant Date (rounded down to the nearest whole number).

5. **Account**.

(a) **Crediting Converted RSUs to Participants' Accounts**. Converted RSUs will vest in full and will be credited to the Participant's Account as of the date the Committee approves the payment of bonuses under the applicable Global Bonus Plan. Such date shall be considered the "**Grant Date**" for purposes of any Converted RSUs and Premium RSUs.

(b) **Crediting Premium RSUs to Participants' Accounts**. Premium RSUs will be credited to the Participant's Account as of the date the Premium RSUs are vested pursuant to Section 4(e) (i.e., upon the first anniversary of the applicable Grant Date, or such other date as specified in the applicable election form and grant notice evidencing the grant of such RSUs). Any Premium RSUs that do not become vested shall be forfeited.

(c) **Cash Dividends**. Whenever any cash dividends are declared on the Shares, the Company will credit the Account of each Participant on the date such dividend is paid with a number of additional RSUs equal to the result of dividing (i) the product of (x) the total number of RSUs credited to the Participant's Account on the record date for such dividend and (y) the per Share amount of such dividend by (ii) the Fair Market Value of one Share on the date such dividend is paid by the Company to the holders of Shares.

(d) **Capitalization Adjustments**. In the event of (i) any change in the Shares through a merger, consolidation, reorganization, recapitalization or otherwise, (ii) a stock dividend, or (iii) a stock split, combination or other changes to the Shares, all as described in Section 3.4 of the Stock Plan, the RSUs granted to each Participant shall be increased or decreased proportionately in accordance with Section 3.4 of the Stock Plan.

6. **Issuance of Shares**. Converted RSUs and Premium RSUs shall be granted under the Stock Plan and shall be considered "Restricted Stock Units" granted pursuant to Section 6.10 of the Stock Plan. Issuance of the Shares underlying the RSUs credited to the Participant's Account shall be made to the Participant (or, in the event of the Participant's death, to the Participant's beneficiary, as provided in Section 8) upon the earlier to occur of (i) the end of the Deferral Period elected by the Participant, (ii) a Change in Control or (iii) a Participant's Separation from Service. For avoidance of doubt, Converted RSUs and Premium RSUs will only be credited to a Participant's Account upon vesting.

(a) **Distribution upon Death**. If a Participant incurs a Separation from Service due to death or his or her death occurs after Separation from Service but before issuance to him or her of the Shares underlying the RSUs credited to his or her Account, then all or the remaining RSUs credited to his or her Account shall be released and the Shares underlying these RSUs shall be issued to such Participant's beneficiaries within 30 days following the date of death.

(b) **Delayed Distribution to Specified Employees**. Notwithstanding any other provision of this Section 6 to the contrary, an issuance of Shares scheduled to be made to a Participant upon his or her Separation from Service who is identified as a Specified Employee as of the date such Participant Separates from Service shall be delayed for a minimum of six months following the Participant's Separation from Service. Any issuance of Shares that otherwise would have been made pursuant to this Section 6 during the six-month period following the Participant's Separation from Service shall be made as soon as administratively practicable, but not later than 90 days after the six-month anniversary of the Participant's Separation from Service. The identification of a Participant as a Specified Employee shall be made by the Committee in its sole discretion in accordance with the terms of this Plan and Sections 416(i) and 409A of the Code and the regulations promulgated thereunder.

7. **Corporate Transaction**. In the event of a Change in Control that constitutes a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the Company's assets under Section 409A, the Shares underlying the RSUs credited to the Account of each Participant shall be converted into shares of the successor entity in accordance with the terms of the Stock Plan or, if elected by the Board, shall be paid to the Participant in a lump sum in cash.

8. **Beneficiary Designation**. Each Participant shall have the right, at any time, to designate any person or persons as his beneficiary or beneficiaries to whom issuance of Shares under this Plan shall be made in the event of his or her death. Any beneficiary designation may be made or changed by a Participant by a written instrument, in such form prescribed by the Company, which is filed with the Company prior to the Participant's death. If a Participant fails to designate a beneficiary, or if all designated beneficiaries predecease the Participant, the Shares underlying the RSUs credited to the Participant's Account shall be issued to the Participant's estate.

9. **Withholding**. The Company will deduct from Plan distributions, or from other compensation payable to a Participant or beneficiary, amounts required by law to be withheld for taxes with respect to benefits under this Plan. The Company reserves the right to reduce any deferral or contribution that would otherwise be made under this Plan on behalf of a Participant by a reasonable amount, and to use all or a portion of this reduction to satisfy the Participant's tax liabilities under this Section 9.

10. **Amendment and Termination**. The Committee may amend or terminate this Plan at any time in whole or in part; provided, however, that no amendment or termination shall reduce the RSUs credited to a Participant's Account (except in the case of any adjustments in accordance with Section 3.4 of the Stock Plan) or adversely affect the rights of a Participant to such RSUs, without the consent of the Participant (or the Participant's beneficiary in the event of the Participant's death). Notwithstanding the foregoing, this Plan may be amended at any time, without the consent of any Participant (or beneficiary) if necessary or desirable to comply with the requirements, or avoid the application, of Section 409A.

11. **General Provisions**.

(a) **Unfunded Plan**. The Company's obligation to grant RSUs and issue Shares under this Plan shall be contractual only and all such grants and issuances hereunder shall be made by the Company from its general assets at the time and in the manner provided for in this Plan. No funds, securities or other property of any nature shall be segregated or earmarked for any current or former Participant, beneficiary or other person, and his or her sole right is as a general creditor of the Company with an unsecured claim against its general assets.

(b) **Non-Alienation of Benefits**. Neither a Participant nor any other person shall have any rights to sell, assign, transfer, pledge, anticipate, or otherwise encumber the RSUs granted under this Plan to the Participant or any other person. Any attempted sale, assignment, transfer or pledge shall be null and void and without any legal effect. No part of the RSUs granted under this Plan shall be subject to seizure or sequestration for the payment of any debts, judgments, alimony or separate maintenance owed by a Participant or any other person, nor be transferable by operation of law in the event of a Participant's or any other person's bankruptcy or insolvency.

(c) **Section 409A**. Notwithstanding any provision of this Plan to the contrary, this Plan will be construed, administered or deemed amended as necessary to comply with the requirements of Section 409A to avoid taxation under Section 409A to the extent Section 409A applies to this Plan. Each benefit hereunder shall constitute a "separately identified" amount within the meaning of Treasury Regulation §1.409-2(b)(2). The Committee, in its sole discretion shall determine the requirements of Section 409A that are applicable to this Plan and shall interpret the terms of this Plan in a manner consistent therewith. Under no circumstances, however, shall the Company or any affiliate or any of its or their employees, officers, directors, service providers or agents have any liability to any person for any taxes, penalties or interest due on the Shares issued or issuable under this Plan, including any taxes, penalties or interest imposed under Section 409A.

(d) **No Stockholder Rights**. Neither the Participant nor any other person shall have any rights as a stockholder of the Company with respect to the RSUs credited to the Participant's Account until the Shares underlying the RSUs are issued to the Participant (or the beneficiary of the Participant).

(e) **Clawback**. This Plan, and any grant of RSUs or issuance of Shares to any Participant made hereunder, is subject to the provisions of the Company's Amended and Restated Clawback Policy, any other clawback policy of the Company and any applicable legislation (e.g., Dodd-Frank), in each case as may be amended from time to time.

(f) **Severability**. If any provision of this Plan shall be held illegal or invalid for any reason, such illegality or invalidity shall not affect the remaining provisions of this Plan, and this Plan shall be enforced as if the invalid provisions had never been set forth herein.

(g) **Successors in Interest**. The obligation of the Company under this Plan shall be binding upon any successor(s) of the Company, whether by merger, consolidation, sale of assets or otherwise, and for this purpose reference herein to the Company shall be deemed to include any such successor(s).

(h) **Governing Law; Interpretation**. To the extent not governed by Federal law, this Plan shall be construed and enforced in accordance with, and governed by, the laws of the State of Delaware, without giving effect to principles of conflict of laws.

(i) **Claims and Review Procedure**.

(i) Informal Resolution of Questions. Any Participant or beneficiary who has questions or concerns about his or her benefits under this Plan is encouraged to communicate with the Company's Senior Director, Total Rewards and Operations. If this discussion does not give the Participant or beneficiary satisfactory results, a formal claim for benefits may be made within one year of the event giving rise to the claim in accordance with the procedures of this Section 11(i).

(ii) Formal Benefits Claim – Review by the Chief Administrative Officer. A Participant or beneficiary may make a written request for review of any matter concerning his or her benefits under this Plan. The claim must be addressed to the QuidelOrtho Corporation Employee Deferred Compensation Plan, Attn: Chief Administrative Officer, 9975 Summers Ridge Road, San Diego, CA 92121. The Chief Administrative Officer shall decide the action to be taken with respect to any such request and may require additional information if necessary to process the request. The Chief Administrative Officer shall review the request and shall issue his or her decision, in writing, no later than 90 days after the date the request is received, unless the circumstances require an extension of time. If such an extension is required, written notice of the extension shall be furnished to the person making the request within the initial 90-day period, and the notice shall state the circumstances requiring the extension and the date by which the Chief Administrative Officer expects to reach a decision on the request. In no event shall the extension exceed a period of 90 days from the end of the initial period.

(iii) Notice of Denied Request. If the Chief Administrative Officer denies a request in whole or in part, he or she shall provide the person making the request with written notice of the denial within the period specified in paragraph (ii) above. The notice shall set forth the specific reason for the denial, reference to the specific Plan provisions upon which the denial is based, a description of any additional material or information necessary to perfect the request, an explanation of why such information is required, and an explanation of this Plan's appeal procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under Section 502(a) of ERISA following an adverse benefit determination on review.

(iv) Appeal to Committee.

(1) A person whose request has been denied in whole or in part (or such person's authorized representative) may file an appeal of the decision in writing to the Committee within 60 days of receipt of the notification of denial. The appeal must be addressed to the QuidelOrtho Corporation Employee Deferred Compensation Plan, Attn: Compensation Committee, 9975 Summers Ridge Road, San Diego, CA 92121. The Committee, for good cause shown, may extend the period during which the appeal may be filed for another 60 days. The appellant and/or his or her authorized representative shall be permitted to submit written comments, documents, records and other information relating to the claim for benefits. Upon request and free of charge, the applicant should be provided reasonable access to and copies of, all documents, records or other information relevant to the appellant's claim.

(2) The Committee's review shall take into account all comments, documents, records and other information submitted by the appellant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination. The Committee shall not be restricted in its review to those provisions of this Plan cited in the original denial of the claim.

(3) The Committee shall issue a written decision within a reasonable period of time but not later than 60 days after receipt of the appeal, unless special circumstances require an extension of time for processing, in which case the written decision shall be issued as soon as possible, but not later than 120 days after receipt of an appeal. If such an extension is required, written notice shall be furnished to the appellant within the initial 60-day period. This notice shall state the circumstances requiring the extension and the date by which the Committee expects to reach a decision on the appeal.

(4) If the decision on the appeal denies the claim in whole or in part, written notice shall be furnished to the appellant. Such notice shall state the reason(s) for the denial, including references to specific Plan provisions upon which the denial was based. The notice shall state that the appellant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claim for benefits. The notice shall describe any voluntary appeal procedures offered by this Plan and the appellant's right to obtain the information about such procedures. The notice shall also include a statement of the appellant's right to bring an action under Section 502(a) of ERISA.

(5) The decision of the Committee on the appeal shall be final, conclusive and binding upon all persons and shall be given the maximum possible deference allowed by law.

(v) Exhaustion of Remedies. No legal or equitable action for benefits under this Plan shall be brought unless and until the claimant has submitted a written claim for benefits in accordance with paragraph (ii) above, has been notified that the claim is denied in accordance with paragraph (iii) above, has filed a written request for a review of the claim in accordance with paragraph (iv) above, and has been notified in writing that the Committee has affirmed the denial of the claim in accordance with paragraph (iv) above; provided, however, that an action for benefits may be brought after the Chief Administrative Officer or the Committee has failed to act on the claim within the time prescribed in paragraph (ii) and paragraph (iv), respectively. A claimant or his or her authorized representative must initiate any such legal action for benefits within the later of twelve months after: (x) the date that the Chief Administrative Officer or the Committee has failed to take any action on the claim within the time prescribed by paragraph (ii) or (iv) above; or (y) the date of the final denial of a claim under this Plan pursuant to paragraph (iv) above. Any legal action brought after such twelve-month time period will be time barred and cannot be brought in any forum. Any legal action in connection with this Plan may only be brought in the United States District Court for the Southern District of California. In any such legal action, claimant may not present any evidence not timely presented to the Chief Administrative Officer or the Committee as part of this Plan's administrative review process set forth in this Section 11(i).

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Legal Name of Subsidiary	Jurisdiction of Incorporation or Organization
Ortho-Clinical Diagnostics Australia Pty Ltd.	Australia
Ortho-Clinical Diagnostics GmbH (Austria branch)	Austria
Ortho-Clinical Diagnostics FinCo S.a.r.l. (Barbados branch)	Barbados
Ortho-Clinical Diagnostics NV	Belgium
Ortho Clinical Diagnostics Do Brasil Produtos Para Saude Ltda.	Brazil
10165 McKellar Court, L.P.	California, United States
Immutopics, Inc.	California, United States
QuidelOrtho Canada Corporation	Canada
Ortho-Clinical Diagnostics Chile SpA	Chile
Quidel China, Ltd.	China
Ortho-Clinical Diagnostics Trading (China) Co. Ltd.	China
Ortho Clinical Diagnostics Biotechnology Development Shanghai Co. Ltd.	China
Ortho-Clinical Diagnostics Trading (China) Co. Ltd (Beijing branch)	China
Ortho-Clinical Diagnostics Trading (China) Co. Ltd. (Hangzhou branch)	China
Ortho-Clinical Diagnostics Medical Technology (Changsha) Co., Ltd.	China
Ortho-Clinical Diagnostics Colombia SAS	Colombia
Ortho-Clinical Diagnostics Czech s.r.o.	Czech Republic
Quidel Corporation	Delaware, United States
Quidel Cardiovascular Inc.	Delaware, United States
Quidel Services, LLC	Delaware, United States
Quidel International, LLC	Delaware, United States
Orca Holdco, Inc.	Delaware, United States
Orca Holdco 2, Inc.	Delaware, United States
Ortho-Clinical Diagnostics U.S. Equipment, LLC	Delaware, United States
Crimson U.S. Assets LLC	Delaware, United States
Crimson International Assets LLC	Delaware, United States
Ortho-Clinical Diagnostics Transport LLC	Delaware, United States
Ortho-Clinical Diagnostics U.S. FinanceCo I, LLC	Delaware, United States
Ortho-Clinical Diagnostics Denmark, filial af Ortho-Clinical Diagnostics Netherlands B.V.	Denmark
Ortho-Clinical Diagnostics MEA	Dubai
Ortho-Clinical Diagnostics Egypt Investment LLC	Egypt
Ortho-Clinical Diagnostics Egypt Services LLC	Egypt
Ortho-Clinical Diagnostics Egypt for Trading and Importation LLC	Egypt
Micro Typing Systems, Inc.	Florida, United States
Quidel France SARL	France
Ortho-Clinical Diagnostics France SAS	France
Quidel Germany, GmbH	Germany
Germany OCD Co GmbH	Germany
Germany OCD Holding GmbH & Co. KG	Germany
Crimson Germany GmbH	Germany
Ortho-Clinical Diagnostics GmbH	Germany
Quidel Hong Kong Limited	Hong Kong

Quidel Diagnostics India Private Ltd.	India
Ortho Clinical Diagnostics India Private Limited	India
Quidel Ireland Limited	Ireland
Quidel Italy S.r.l.	Italy
Ortho-Clinical Diagnostics Italy S.r.l.	Italy
Ortho-Clinical Diagnostics K.K.	Japan
Ortho-Clinical Diagnostics Luxembourg S.a.r.l.	Luxembourg
Ortho-Clinical Diagnostics S.a.r.l.	Luxembourg
Ortho-Clinical Diagnostics Holdings Luxembourg S.a.r.l.	Luxembourg
Ortho-Clinical Diagnostics FinCo S.a.r.l.	Luxembourg
BioHelix Corporation	Massachusetts, United States
Ortho-Clinical Diagnostics Mexico Operations S. de R.L. de C.V.	Mexico
Ortho-Clinical Diagnostics Mexico Services S. de R.L. de C.V.	Mexico
OCD Investment Holdings B.V.	Netherlands
Ortho-Clinical Diagnostics Netherlands B.V.	Netherlands
Ortho-Clinical Diagnostics NV (Dutch branch)	Netherlands
Ortho-Clinical Diagnostics FinCo S.a.r.l. (US branch)	New York, United States
Ortho-Clinical Diagnostics, Inc.	New York, United States
Ortho-Clinical Diagnostics Australia Pty Ltd. (New Zealand branch)	New Zealand
Ortho-Clinical Diagnostics Norway (branch of Ortho-Clinical Diagnostics Netherlands B.V.)	Norway
Diagnostic Hybrids, Inc.	Ohio, United States
Ortho-Clinical Diagnostics Panama S.A.	Panama
Ortho-Clinical Diagnostics Panama Export S.A.	Panama
Ortho-Clinical Diagnostics Philippines Inc.	Philippines
OCD Clinical Diagnostics Portugal, Unipessoal Lda	Portugal
Ortho-Clinical Diagnostics Netherlands B.V. (Puerto Rico branch)	Puerto Rico
Ortho-Clinical Diagnostics Limited Liability Company	Russia
Branch of Ortho-Clinical Diagnostics Netherlands B.V. (Saudi Arabia branch)	Saudi Arabia
QuidelOrtho Regional Headquarters Company	Saudi Arabia
Ortho-Clinical Diagnostics Singapore Pte. Ltd.	Singapore
Ortho-Clinical Diagnostics Singapore Pte., Ltd, Korea branch	South Korea
Ortho-Clinical Diagnostics Spain, S.L.	Spain
Ortho-Clinical Diagnostics Sweden AB	Sweden
Ortho-Clinical Diagnostics Switzerland GmbH	Switzerland
Ortho-Clinical Diagnostics GmbH (Swiss branch)	Switzerland
Ortho-Clinical Diagnostics (Thailand) Ltd.	Thailand
QuidelOrtho Health Operational Services Limited Company	Turkey
Quidel UK Limited	United Kingdom
Ortho Clinical Diagnostics Holdings Limited	United Kingdom
Crimson OCD (UK) Limited	United Kingdom
Ortho-Clinical Diagnostics	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-265354) pertaining to the QuidelOrtho Corporation Amended and Restated 2018 Equity Incentive Plan and the QuidelOrtho Corporation Amended and Restated 1983 Employee Stock Purchase Plan, and,
(2) Post-Effective Amendment No. 1 to Registration Statement (Form S-8 No. 333-262434) pertaining to the Quidel Corporation 2016 Equity Incentive Plan, Quidel Corporation 2010 Equity Incentive Plan, Quidel Corporation Amended and Restated 2001 Equity Incentive Plan, Ortho Clinical Diagnostics Holdings plc 2021 Omnibus Incentive Award Plan, and Ortho-Clinical Diagnostics Bermuda Co. Ltd. 2014 Equity Incentive Plan;

of our reports dated February 29, 2024, with respect to the consolidated financial statements of QuidelOrtho Corporation and the effectiveness of internal control over financial reporting of QuidelOrtho Corporation included in this Annual Report (Form 10-K) of QuidelOrtho Corporation for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California
February 29, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Iskra, certify that:

1. I have reviewed this annual report on Form 10-K of QuidelOrtho Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2024

/s/ MICHAEL S. ISKRA

Michael S. Iskra

Interim Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph M. Busky, certify that:

1. I have reviewed this annual report on Form 10-K of QuidelOrtho Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2024

/s/ JOSEPH M. BUSKY

Joseph M. Busky

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

Certifications by the Principal Executive Officer and Principal Financial Officer of Registrant Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Each of the undersigned hereby certifies, in his capacity as an officer of QuidelOrtho Corporation, a Delaware corporation (the "Company"), for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- the Company's Annual Report on Form 10-K for the period ended December 31, 2023 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 29, 2024

/s/ MICHAEL S. ISKRA

Michael S. Iskra

Interim Chief Executive Officer

(Principal Executive Officer)

/s/ JOSEPH M. BUSKY

Joseph M. Busky

Chief Financial Officer

(Principal Financial Officer)

Exhibit 97.1

QuidelOrtho Corporation

Amended and Restated
Clawback Policy

1. PURPOSE

QuidelOrtho Corporation (the "**Company**") is committed to conducting business with integrity, in accordance with high ethical standards and in compliance with all applicable laws, rules and regulations, including those regarding the presentation of the Company's financial information to the public. As a result, the Board of Directors of the Company (the "**Board**") has adopted this Clawback Policy (as amended from time to time, this "**Policy**") effective as of the Effective Date. This Policy replaces in its entirety the Company's prior Clawback Policy dated May 27, 2022 (the "**Prior Policy**"). Notwithstanding the foregoing, this Policy shall not affect any remedies or rights of recoupment that may become available to the Company under the Prior Policy with respect to any incentive compensation (or any portion thereof) that (i) was made, granted or Received prior to the Effective Date and (ii) is not recoverable under this Policy.

2. ADMINISTRATION

This Policy is administered by the Compensation Committee of the Board (the "**Committee**") and is intended to comply with, and as applicable to be administered and interpreted consistent with, Listing Rule 5608 adopted by the Nasdaq Stock Market to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "**Rule 10D-1**"). Except as limited by law, the Committee has full power and authority to apply this Policy. Any determinations made by the Committee will be final, conclusive and binding on all affected individuals.

The Board or Committee may amend, modify or terminate this Policy in whole or in part at any time in its sole discretion and may adopt such rules and procedures that it deems necessary or appropriate to implement this Policy or to comply with applicable laws and regulations.

3. CLAWBACK TRIGGERS

In the event that the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws (including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (other than corrections resulting from changes to accounting standards), the Company will recover on a reasonably prompt basis the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received based upon the restated financial statements.

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess amount of Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total shareholder return, the Committee will determine the amount based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total shareholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined on a pre-tax basis.

The Company shall enforce any recovery pursuant to this Policy by requiring payment of such amount(s) to the Company, by set-off, by reducing future compensation, or by all legal means or combination of means available as the Committee determines appropriate. Any right of recoupment or

recovery under this Policy shall apply irrespective of whether the Covered Executive is an employee of the Company at such time. The Company need not recover the excess amount of Incentive-Based Compensation if and to the extent that the Committee determines that such recovery is impracticable and not required under Rule 10D-1, including if the Committee determines that the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such amounts, or recovery would impact the qualified status of a tax-qualified retirement plan. No recovery of compensation under this Policy will be an event giving rise to a right to resign for "good reason" or be deemed a "constructive termination" (or any similar term) as such terms are used in any agreement between any Covered Executive and the Company.

4. DEFINITIONS

1. "**Covered Executives**" means any executive officer of the Company as defined in accordance with Rule 10D-1 under the Securities Exchange Act of 1934, as amended.

2. "**Financial Reporting Measure**" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.

3. "**Incentive-Based Compensation**" means any compensation that is granted, earned or vested based wholly or in part on the Company's attainment of any Financial Reporting Measure, including annual bonuses and other short- and long-term cash, equity and equity-based incentive awards, that was Received by a person (i) on or after October 2, 2023 and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation. Incentive-Based Compensation is deemed to be "**Received**" in the fiscal period during which the relevant financial reporting measure is attained, regardless of when the compensation is actually paid or awarded.

4. "**Recovery Period**" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy and any "transition period" as prescribed under Rule 10D-1.

5. NOT EXCLUSIVE

Any right of recoupment or recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights that may be available to the Company, including (i) pursuant to the terms of any Company plan or policy or any agreement with the Covered Executive, (ii) disciplinary action up to and including termination, and (iii) any other legal remedies available to the Company (including Section 304 of the Sarbanes-Oxley Act of 2002); provided that the Company shall not recoup amounts pursuant to such other plan, policy, agreement, remedies or rights to the extent it is recovered pursuant to this Policy).

6. NO INDEMNIFICATION

The Company will not indemnify any Covered Executive against any loss pursuant to this Policy, nor will the Company pay or agree to pay any insurance premium to cover any loss hereunder.

Effective Date: October 2, 2023