QuidelOrtho™

Focused Progress, Lasting Impact

2024 Annual Report

"With a determined focus on our goals, we are creating a future that is as purposeful as it is promising."

– Brian J. Blaser, President and CEO

To our valued stockholders

2024 was an important year for QuidelOrtho—one where we made decisive changes and began executing key components of our strategy to position our business for long-term success. While managing change is never without its challenges, we took this opportunity to build upon our strengths, address areas requiring improvement, and focus on achieving three key objectives:

- Delivering an exceptional customer experience
- Prioritizing effective execution
- Driving profitable, sustainable growth

Having taken the helm in May 2024, I, along with our leadership team, undertook an extensive review of every aspect of our business and product portfolio. I had the opportunity to meet with and gather feedback from our team, customers, suppliers, and investors. Those insights helped inform our mission-critical, near-term priorities. As a result, we refocused our efforts on a narrow set of programs that we expect can yield sustainable growth and profitability. We believe these efforts are showing early signs of progress.

2024 in review

We had a solid finish to the year with $2.8 billion in revenue. We saw considerable strength in our core businesses even as demand for our COVID-19 tests came down to what we expect to be endemic levels. Our Labs business, which represented more than half of our total 2024 revenue, demonstrated solid underlying mid-single digit growth*, strong brand recognition, long-term contracts to support a predictable business model, and a loyal customer base. Our Point of Care business continued its leadership position with Sofia®'s large global installed base and strong sales of our Flu / COVID-19 combination test. Our Transfusion Medicine business remained the #1 global brand leader in Immunohematology, and our Molecular Diagnostics business initiated clinical trials in support of the launch of our U.S. Savanna® respiratory product. Importantly, the foundation of our business was strong as demonstrated by our recurring revenue of over 90% in 2024.

Operationally in 2024, we took the necessary steps to drive meaningful progress across the business by sharpening our focus in research and development (R&D), with emphasis on improving productivity and expanding our assay menu content. We strengthened our senior leadership team with the addition of Jonathan Siegrist, Ph.D. as our Executive Vice President of Research and Development and Chief Technology Officer, and Lee Bowman as our Chief Human Resources Officer, to bring together the right team to meet our goals. In addition, we realigned our leadership structure to be a flatter, more agile organization to increase our customer focus, reduce complexity, and improve our efficiency and cost structure. Further, recognizing the value of a unified global leadership team, we aligned our global regions with our business units.

* Excludes COVID-19 and non-core revenues, on a constant-currency basis. Please see reconciliation of non-GAAP measures included in this report for reconciliation to the closest GAAP metric.

At the same time, we were disciplined in executing our cost-savings initiatives, which were designed to improve both near-term performance and long-term durable growth. The goal of these initiatives is to restore margins, improve business efficiencies, and increase operational savings. I am pleased to report that we expect to realize the remainder of our previously announced $100 million in annualized cost-savings by mid-2025. Further, we have implemented new initiatives targeted at improving procurement savings. We also made progress in strengthening our balance sheet and improving cash flow, with debt reduction continuing to be our highest capital allocation priority.

Lastly, we appointed two experienced board members in 2024, and we will continue to operate as good company stewards in 2025 and beyond with our strong board of directors.

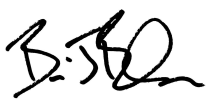
A clear and focused path forward

One of our top priorities in 2025 is to continue building upon our continuous improvement culture. By making tough but necessary organizational changes, we have strengthened our operations to better meet the demand for our global diagnostic solutions. As we advance our R&D efforts, expand our assay menus, and introduce new platforms over time, we expect to enhance our competitive market position.

We will focus on improving our business with a critical eye on the most direct path toward profitable and sustainable growth in 2025 and in the years ahead. With a determined focus on our goals, we are creating a future that is as purposeful as it is promising.

I want to thank our employees for their dedication during this time of transition, as we navigate changes with the firm belief that they can strengthen our organization and lay the foundation for future growth. I also wish to thank our customers around the world who rely on our products to support expedient care of their patients, and our stockholders for their continued support.

Sincerely,



Brian J. Blaser
QuidelOrtho President & Chief Executive Officer

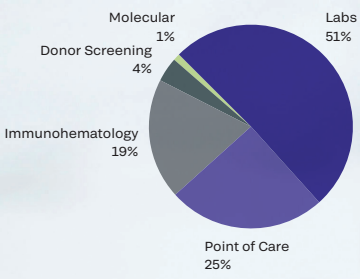
Full-Year 2024 Highlights[1]

Total Revenue
$2.78B
(7%) y/y[1]

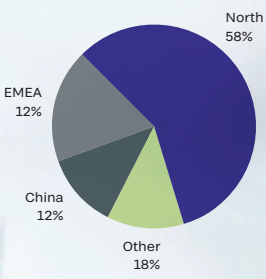
Adjusted EBITDA
$543M[2]
20% Margin[2]

Adjusted Diluted EPS
$1.85[2]
(55%) y/y[2]

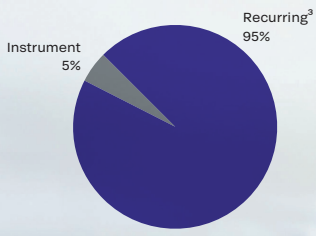
Business Unit



Geography



Category



[1] Revenue growth rates are shown on a constant currency basis; the term "constant currency" means we have translated local currency revenues for all reporting periods to U.S. dollars using internally derived currency exchange rates held constant for each period. This additional non-GAAP financial information is not meant to be considered in isolation from or as a substitute for financial information prepared in accordance with GAAP. Please see reconciliation of non-GAAP measures included in this report for reconciliation to the closest GAAP metric.

[2] Please see reconciliation of non-GAAP measures included in this report for reconciliation to the closest GAAP metric.

[3] Recurring revenue means revenues from sales of our assays, reagents, consumables and services, and excludes instruments.

Reconciliation of Non-GAAP Financial Information

Full-Year 2024 Revenue

(In millions, unaudited)

	Fiscal Year Ended				
	December 29, 2024	December 31, 2023	% Change	Currency Impact	Constant Currency[a]
Respiratory revenues	$ 503.9	$ 714.6	(29.5)%	— %	(29.5)%
Non-Respiratory revenues	2,279.0	2,283.2	(0.2)%	(0.8)%	0.6%
Total revenues[b]	$2,782.9	$2,997.8	(7.2)%	(0.6)%	(6.6)%

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

(b) The fiscal year ended December 31, 2023 includes an approximate $19 million settlement award from a third party related to one of the Company's collaboration agreements.

Adjusted Net Income

(In millions, except per share data; unaudited)

	Fiscal Year Ended			
	December 29, 2024	Diluted EPS	December 31, 2023	Diluted EPS
Net (loss) income	$(2,052.0)	$(30.54)	$(10.1)	$(0.15)
Adjustments:				
Amortization of intangibles	203.4		204.8	
Acquisition and integration costs	127.2		113.4	
Goodwill impairment charge	1,822.6		—	
Asset impairment charge	56.9		4.5	
Asset write off	20.0		—	
Incremental depreciation on PP&E fair value adjustment	35.1		33.5	
Amortization of deferred cloud computing implementation costs	14.7		9.2	
Loss on disposal	1.2		—	
EU medical device regulation transition costs	2.0		2.5	
Employee compensation charges	5.6		—	
Credit Agreement amendment fees	4.0		—	
Non-cash interest expense for deferred consideration	—		0.7	
(Gain) loss on investments	(0.7)		3.6	
Other adjustments	4.0		1.7	
Income tax impact of adjustments	(174.6)		(87.5)	
Discrete tax items	55.6		(11.2)	
Adjusted net income	$ 125.0	$ 1.85	$277.7	$ 4.13
Weighted-average shares outstanding - diluted		67.4		67.3

Labs Revenue

(In millions, unaudited)

	Fiscal Year Ended				
	December 29, 2024	December 31, 2023	% Change	Currency Impact	Constant Currency[a]
Total Labs revenue	$1,426.7	$1,425.4	0.1%	(0.9)%	1.0%
COVID-19 revenue	(2.5)	(8.3)			
Non-core revenue[b]	(94.2)	(125.0)			
Total Labs revenue, ex-COVID-19 and non-core revenues	$1,330.0	$1,292.1	2.9%	(1.0)%	3.9%

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

(b) Full-year 2024 non-core revenue includes revenue from contract manufacturing. Full-year 2023 non-core revenue includes revenue from contract manufacturing and a third-party settlement.

Adjusted EBITDA

(In millions, unaudited)

	Fiscal Year Ended
	December 29, 2024
Net (loss) income	$(2,052.0)
Depreciation and amortization	453.4
Interest expense, net	163.5
Provision for (benefit from) income taxes	(79.5)
Acquisition and integration costs	127.2
Goodwill impairment charge	1,822.6
Asset impairment charge	56.9
Asset write off	20.0
Amortization of deferred cloud computing implementation costs	14.7
Loss on disposal	1.2
EU medical device regulation transition costs	2.0
Employee compensation charges	5.6
Credit Agreement amendment fees	4.0
(Gain) loss on investments	(0.7)
Other adjustments	4.0
Adjusted EBITDA	$ 542.9
Total revenues	$ 2,782.9
Adjusted EBITDA margin	19.5%

Forward-looking statements

This report of QuidelOrtho Corporation ("QuidelOrtho" or the "Company") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are any statement contained herein that is not strictly historical, including, but not limited to, QuidelOrtho's future financial condition and operating results, including expected results of cost-savings initiatives, and other future plans, objectives, strategies, expectations and intentions. Without limiting the foregoing, the words "may," "will," "could," "would," "should," "might," "expect," "anticipate," "believe," "estimate," "plan," "intend," "goal," "project," "strategy," "future," "continue," "aim," "strive," "seek," 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 QuidelOrtho's management as of today 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: fluctuations in demand for QuidelOrtho's non-respiratory and respiratory products; 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 business combination of Quidel Corporation and Ortho Clinical Diagnostics Holdings plc; and other macroeconomic, geopolitical, market, business, competitive and/or regulatory factors affecting the business of QuidelOrtho generally, including those discussed in QuidelOrtho's Annual Report on Form 10-K for the fiscal year ended December 29, 2024 and subsequent reports filed with the Securities and Exchange Commission (the "Commission"), including under Part I, Item 1A, "Risk Factors" of the Form 10-K. You should not rely on forward-looking statements as predictions of future events because these statements are based on assumptions that may not come true and are speculative by their nature. All forward-looking statements are based on information currently available to QuidelOrtho and speak only as of the date hereof. QuidelOrtho undertakes no obligation to update any of the forward-looking information or time-sensitive information included in this report, whether as a result of new information, future events, changed expectations or otherwise, except as required by law.

Non-GAAP financial measures

This report contains financial measures that are considered non-GAAP financial measures under applicable rules and regulations of the Commission, including but not limited to "constant currency revenue changes," "constant currency Labs revenue changes, excluding COVID-19 and non-core revenues," "adjusted EBITDA," "adjusted EBITDA margin," "adjusted diluted EPS," and other non-GAAP financial measures included in the reconciliation tables in this report. These non-GAAP financial measures should be considered supplemental to, and not a substitute for, financial information prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). These non-GAAP financial measures eliminate impacts of certain non-cash, unusual or other items that the Company does not consider indicative of its ongoing operating performance, and the Company generally uses these non-GAAP financial measures to facilitate management's financial and operational decision-making, including evaluation of the Company's historical operating results and comparison to competitors' operating results. The Company's definitions of these non-GAAP measures may differ from similarly titled measures used by others. These non-GAAP financial measures reflect an additional way of viewing aspects of the Company's operations that, when viewed with GAAP results and the reconciliations to corresponding GAAP financial measures, may provide a more complete understanding of factors and trends affecting the Company's business. Because non-GAAP financial measures exclude the effect of items that will increase or decrease the Company's reported results of operations, management strongly encourages investors to review the Company's consolidated financial statements and reports filed with the Commission in their entirety. Reconciliations of the non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the tables in this report.

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 29, 2024

OR

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

For the transition period from _____ to _____

Commission file number: 001-41409

QUIDELORTHO CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**87-4496285**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9975 Summers Ridge Road, San Diego, California 92121

(Address of principal executive offices, including zip code)

(858) 552-1100

(Registrant's telephone number, including area code)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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 $2,182,619,277 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 19, 2025, 67,446,544 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 2025 Annual Meeting of Stockholders (scheduled to be held on May 20, 2025) 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 29, 2024

TABLE OF CONTENTS

Future Uncertainties and Forward-Looking Statements

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, and Section 21E of 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," "could," "would," "should," "might," "expect," "anticipate," "believe," "estimate," "plan," "intend," "goal," "project," "strategy," "future," "continue," "aim," "strive," "seek" 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: fluctuations in demand for our non-respiratory and respiratory products; 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; 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 ended 2024," "fiscal year ended 2023" and "fiscal year ended 2022" in this Annual Report refer to the Company's fiscal years ended December 29, 2024, December 31, 2023 and January 1, 2023, respectively. Refer to the Summary of Abbreviated Terms at the end of this Annual Report for definitions of terms used throughout 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 support clarity for 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 POC settings, blood banks and donor centers, as well as for individual, non-professional, OTC use.

On May 27, 2022, pursuant to the BCA, Quidel and Ortho consummated the Combinations and each of Quidel and Ortho became a wholly owned subsidiary of QuidelOrtho. For additional information about the Combinations, 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. Effective January 1, 2024, Japan and Asia Pacific operating segments were combined into one operating segment: JPAC. North America, EMEA and China are the Company's reportable segments; Latin America and JPAC are immaterial operating segments that are not considered reportable segments and are included in "Other." We generate our revenue in the following business units: Labs, Transfusion Medicine (Immunohematology and Donor Screening product categories), Point of Care and Molecular Diagnostics. We also generate non-core revenue, including through our contract manufacturing business and certain business collaborations. In February 2024, we initiated a plan to transition out of our U.S. donor screening portfolio through the wind-down of the VIP platform and microplate assays, which are only sold in the U.S., and have a lower growth and margin profile. 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 "—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 Optix™, Ortho Plus®, ORTHO VISION®, QuickVue®, Quidel®, QuidelOrtho™, QVue™, Savanna®, Sofia®, Solana®, Thyretain®, Triage®, ValuMetrix®, 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
	Specialized diagnostic solutions
	Other product revenues primarily from contract manufacturing [(1)]
	Collaboration and license agreements pursuant to which we derive collaboration and royalty revenues [(1)]
Molecular Diagnostics	Tests for 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	Transfusion Medicine business unit includes two product categories:
	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

(1) Represents our non-core revenue. All non-core revenue is recorded in the North America segment.

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 & Bioassays	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
	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, 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/ hMPV, Respiratory Viral Panel 4 (SARS-CoV-2, RSV, 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
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	Influenza A+B, Influenza A+B & SARS-CoV-2 Ag, RSV, Strep A, SARS-CoV-2 Ag
Non-respiratory Infectious Diseases	Adenoviral Conjunctivitis, Chlamydia, Clostridium Difficile (organism), Legionella, Lyme Disease, S. pneumoniae
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 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	
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 29, 2024, we had approximately 1,100 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 75% 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−Five 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, 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 help 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 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, Becton-Dickinson, 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 stockholder returns.

The competitive strengths that serve as our foundation of success today and can drive future growth include three key aspects, all of which benefit from our talented people and loyal customers:

- **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.
- **Strong commercial footprint.** We leverage our commercial team of more than 2,700 teammates in sales, service and marketing across more than 130 countries to facilitate successful delivery of innovative solutions to meet customer and patient needs across the healthcare continuum.
- **POC Leadership.** We are a recognized leader in POC diagnostics, providing rapid, accurate and reliable solutions that empower providers to make informed decisions at the moment of care. Our Sofia and Triage platforms are trusted across urgent care clinics, physician offices and other decentralized settings.

Business Strategy

We are driven to transform diagnostics into action for more people in more places. To achieve this, we serve a broad range of market segments across the healthcare continuum, from large centralized laboratories to physicians' offices and other decentralized settings. While these care settings have traditionally been less integrated, the healthcare landscape continues to become more integrated. This consolidation is bringing together labs, hospitals, physicians' offices and urgent care clinics into unified healthcare systems. This integration means that success in one care setting often creates opportunities in others within the same system.

Central to our strategy is a focus on economic profit and return on invested capital (ROIC) across all aspects of our business. We are committed to allocating resources and capital efficiently and seek to deliver sustainable returns above the cost of capital. By prioritizing opportunities that can maximize economic profit, we aim to create value for our stakeholders while maintaining a disciplined approach to growth.

In the near term, we are focusing on a set of strategic initiatives across our lines of business and geographies to improve the underlying business and deliver greater stockholder value.

Our near-term priorities include:

- capturing market share in high-value profit pools where we hold a strong competitive position;
- building a culture focused on driving sales growth, profitability, cash flow and returns for stockholders;
- aligning incentive structures with both customer and stockholder value creation; and
- developing and executing a comprehensive talent management strategy.

Longer term, we plan to continue to build and enhance our award-winning customer service, invest in platform capabilities and improve our assay menus. Recognizing the complexity and speed of innovation in these areas, we will explore partnerships where we find strategic and financial alignment. This approach allows us to mitigate risk, accelerate innovation and deliver solutions to market more efficiently.

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, including new and improved assays and software;
- support of important life-cycle-management efforts to maintain our current on-market portfolio of products; 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, 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 are also exploring strategic partnerships as part of our R&D process.

R&D expenses were $218.7 million, $245.0 million and $187.9 million for fiscal years ended 2024, 2023 and 2022, respectively, which includes the impact of Ortho's operations from the date of the Combinations. We anticipate a continued appropriate investment of our financial resources to product and technology R&D for the foreseeable future, with increases and decreases as projects progress through the various development phases.

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. 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.

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 and JPAC (Japan and Asia Pacific) are immaterial operating segments that are not considered reportable segments and are included in "Other." We generate our revenue in the following business units: Labs, Transfusion Medicine (Immunohematology and Donor Screening product categories), Point of Care and Molecular Diagnostics. We also generate non-core revenue, including through our contract manufacturing business and certain business collaborations.

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. Under this model, our customers are required 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 sales force for each of our business units. 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. In the past few years, we have evolved our North America sales force to be specialized as product experts and invested in new business development roles strategically to expand our market footprint in independent reference laboratory, urgent care and oncology markets. 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 China and the Asia Pacific region, which includes 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 efforts to demonstrate 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. For fiscal year ended 2024, one customer represented 11% of Total revenues. Refer to 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 Carlsbad, California, San Diego, California, Athens, Ohio, Raritan, New Jersey, Rochester, New York, Pompano Beach, Florida, and Pencoed, Wales.

Our Carlsbad, California lateral flow manufacturing facility consists 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. This facility operates under a QMS per ISO standard and regulatory regulations and is certified to ISO 13485:2016 and MDSAP medical device standards. Many of the immunoassay products manufactured at this facility 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, drugs of abuse and molecular diagnostic 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 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 methods 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. While we encountered increasing pressures on raw material pricing during fiscal years ended 2023 and 2022, inflationary impacts during fiscal year ended 2024 lessened and returned closer to pre-COVID-19 pandemic levels. To help mitigate these supply chain challenges, we (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, (iii) create redundancy in our global supply chain and (iv) insource activity where it makes strategic and financial sense. 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, refer to 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.

The Company has an ongoing 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 arrangement is governed by the Grifols Agreement, 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 fiscal year ended 2024, 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 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 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 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 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 EUA, for certain emergency circumstances after the Secretary of the 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 CLIA regulates laboratory testing and requires clinical laboratories to be certified by their state, as well as the 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 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 IVD 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 biologic IVDs may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, and when appropriate, animal studies performed in accordance with the FDA's Good Laboratory Practice requirements;
- submission to the FDA of an 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 or biologic IVD product to humans and human specimens;
- 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 IVD product candidate for its intended purpose;
- preparation of and submission to the FDA of a 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 and intended uses. 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 CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for use 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 biologic IVDs 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. In addition, a summary of every manufactured lot of product must be submitted to the FDA for review and approval prior to distribution. 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 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 MDR and 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, and the transition period provided for in the EU MDR for existing certifications issued under the previous Medical Devices Directive ended 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 June 2024, the European Parliament and the Council adopted a staggered extension of its transition period, for certain existing certifications, ranging from December 31, 2027 for high risk IVDs, December 31, 2028 for medium risk IVDs, December 31, 2029 for lower risk IVDs and December 31, 2030 for certain provisions concerning devices manufactured and used in health institutions (EU 2024/1860). 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 NMPA, 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 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;
- 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 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, as amended by the 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, to provide rights to California residents in relation to their personal information, and to conduct audits for certain higher risk data processing. 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, in addition to the California Attorney General's existing enforcement authority. Similar laws have gone into effect or passed in other states, though most state laws exempt entities that are subject to HIPAA, unlike the CCPA, which only has a data-level exemption. 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. Additionally, certain U.S. state laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information, specifically;

- the FTC and U.S. state Attorneys General often rely on Section 5 of the FTC Act and state consumer protection laws, respectively, to enforce inadequate privacy and data security practices. Section 5 of the FTC Act and state consumer protection laws provide the FTC and state Attorneys General, respectively, with broad authority to protect consumers from unfair or deceptive acts or practices;
- in the EEA and U.K., 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 of persons 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 personal data, enforcement notices or assessment notices (for a compulsory audit), civil claims including representative actions and other class action type litigation;
- EU and U.K. rules with respect to cross-border transfers of personal data out of the EEA and the U.K., respectively, which are in flux, including in light of a decision by the Court of Justice of the EU invalidating the EU-U.S. Privacy Shield Framework, the European Commission's publishing of revised SCCs in 2021, and the U.K. IDTA and Addendum to the SCCs (the "Addendum") that came into effect on March 21, 2022, which we must consider and apply, where applicable. When relying on SCCs or the U.K. IDTA and Addendum, 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 or U.K. IDTA and Addendum 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 EU-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 EU-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 EU, 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 EU 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 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, among other penalties, fines of up to RMB 500,000 for the relevant entity as well as RMB 100,000 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 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 China, which are designed to provide further supplemental guidance in accordance with the laws mentioned above;

- Canada's 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. Quebec's Law 25 and other provincial laws governing personal information also impose additional data subject rights and obligations that have recently taken effect;
- 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;
- enacted or considered legislation similar to the above in other countries around the world, in which we do business, including Brazil's General Data Protection Law (*Lei Geral de Proteção de Dados Pessoais*), Chile's Personal Data Protection Law, Mexico's Federal Law on Protection of Personal Data Held by Private Parties (*Ley Federal de Protección de Datos Personales en Posesión de los Particulares*) and Panama's Personal Data Protection Law (*Ley sobre Protección de Datos Personales*), which impose requirements for processing personal data about persons in those jurisdictions; and
- 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.

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 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 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 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 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 sustainability requirements applicable to our government contracts, and failure to address these laws and regulations, sustainability 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 Sustainability Strategies

Human Capital Resources

As of December 29, 2024, we had approximately 6,600 employees worldwide, with approximately 3,700 employees in the U.S. and approximately 2,900 employees outside of the U.S. We employ approximately 1,800 manufacturing employees and approximately 2,700 employees in commercial sales, service and regional marketing positions worldwide, including approximately 1,100 service teammates. Approximately 16% 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.

Inclusion and Belonging

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 experiences and collective strengths drive creative solutions, breakthrough innovation and highly productive teams.

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 based on merit. We prohibit discrimination that is unlawful by federal, state or local law. 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 inclusion in mind. We have established defined core behaviors based on the QuidelOrtho Way, which defines 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 an inclusive and positive 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 these core behaviors by incorporating other inclusive 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.

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 creating opportunities for employee engagement and input to drive continuous improvement, which in turn can minimize recordable incidents and improve 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 initiatives and philanthropic programs−We contribute to a variety of community initiatives and philanthropic programs, including research partnerships, blood drive sponsorships, scholarship and internship programs, as well as STEM and STEAM programs with educational institutions.

Sustainability Strategy

We are driven by a purpose to improve the quality of life for people all over the world through our diagnostic solutions – providing vital health information when and where it is needed 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 environmentally responsible to support practitioners and provide better outcomes for patients. Through our corporate actions in the areas of environmental sustainability, social responsibility, ethics, corporate and ESG-related governance, and supply chain responsibility, we seek to positively impact our communities and stakeholders while driving value for 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 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. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future. 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 segments;
- 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, including 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;
- legal and regulatory risks, reputational harm or other adverse business consequences as a result of implementing artificial intelligence ("AI") and machine learning technologies;
- risks associated with our non-U.S. operations and international sales, including currency translation risks, the impact of possible new sanctions or 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 integration-related costs;
- our inability to protect our information systems and personal and confidential information, including from data corruption, cyber-attacks, security breaches or IT errors;
- 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 inability to adequately manage our clinical studies;
- failure to comply with applicable regulations by the FDA and other federal, state and foreign regulatory agencies, which may result in significant costs, the suspension or withdrawal of previously obtained regulatory approvals, product recalls, seizure of products or injunctions against the distribution of our products, operating restrictions and criminal prosecution;
- 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 contracts with government entities;
- liability claims and harm to our reputation resulting from claims that our products are defective or do not comply with applicable regulations;
- failure to comply with applicable healthcare laws and regulations, laws and regulations associated with our use of hazardous materials, anti-bribery and 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;
- our need to raise additional funds to finance our future capital or operating needs or other business purposes;
- risks related to our indebtedness;
- our inability 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;
- identified material weaknesses in our internal controls;
- the outcomes of legal proceedings instituted against us;
- additional costs and new risks associated with sustainability 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; and
- risks associated with future sales of our common stock by us or our stockholders in the public market.

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 segments 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 deliver 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, high 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 conflicts in Ukraine and the Middle East, or increasing regulation in 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 18% of our total revenues for the year ended December 29, 2024. 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 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. New or increased quotas, duties or tariffs, or threats or changes in policy with respect to such trade restrictions, 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, including an effort to reduce costs, which could adversely affect our business, financial condition and results of operations.

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 plan to transition out of our U.S donor screening portfolio through the wind-down of the VIP platform and microplate assays, which are only sold in the U.S. and have a lower growth and margin profile. 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.

We have been incorporating AI into our internal operations and may incorporate AI into our products and services. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business.

We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our internal operations and may incorporate AI into our products and services, which may enhance their operation and effectiveness internally and for our customers, suppliers, and consumers. There can be no assurance that we or our customers will realize the expected benefits from such implementation of AI. AI innovation presents risks and challenges that could impact our business. Our, or our vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information. Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant, which may result in the development of products that are subsequently unacceptable under new or revised regulatory frameworks. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, some AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cybersecurity risks, reputational harm, and legal liability.

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 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 regulations in the U.S., EU and other jurisdictions impacting the marketing of our products, U.S. laws on import/export limitations, the FCPA, and local laws prohibiting corrupt payments to governmental officials, including anti-corruption laws in China;
- lost revenue as a result of macroeconomic developments, including the inflationary environment and recessionary fears;
- the imposition or threat of, or changes in policy regarding, trade barriers (such as sanctions, tariffs, quotas, preferential bidding, import restrictions or other barriers) by U.S. or foreign governments;
- 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;

- U.S. or 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 conflicts in Ukraine and the Middle East, 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 Our Integration and Business Efficiency 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 business efficiencies 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 and our business efficiency initiatives, including the synergies, cost savings or sales or growth opportunities that we expect, 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 our business efficiency initiatives within the anticipated timeframe, our business, financial condition and operating results may be adversely affected.

We will continue to incur significant integration-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 integration and implementation expenses 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, including from data corruption, cyber-attacks, security breaches or IT errors, 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, are 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, refer to 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.

Furthermore, in recent years, the U.S. Supreme Court has ruled on several patent cases and several laws have been enacted that, in certain situations, potentially narrow the scope of patent protection available and weaken the rights of patent owners. As a result, companies may pursue an "efficient infringement" strategy, having concluded that it is cheaper to infringe third-party intellectual property rights than to acquire, license or otherwise respect them. There can be no assurance that we will be successful in securing additional patents on commercially desirable improvements, that such additional patents will adequately protect our innovations or offset the effect of expiring patents, or that competitors will not be able to design around our patents.

In addition, third parties may challenge our issued patents through procedures such as Inter-Partes Review ("IPR"). In many IPR challenges, the U.S. Patent and Trademark Office (the "PTO") may cancel or significantly narrow issued patent claims. IPR challenges could increase the uncertainties and costs associated with the maintenance, enforcement and defense of our issued and future patents and could have an adverse effect on our business, financial condition and results of operations. Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary

patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent owner can request unitary effect, thereby getting a European patent with unitary effect (a "Unitary Patent"). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that we request to be treated or obtain as Unitary Patents remain under the jurisdiction of the UPC and may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

Certain of our intellectual property rights are held through license agreements and collaboration arrangements with third parties. If we cannot retain these agreements or arrangements, we may not be able to sell, develop or commercialize our products. 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, intellectual property assignment 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 be enforceable or provide meaningful protection for our proprietary technology information in the event of unauthorized use or disclosure or other breaches of the agreements, or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to our brands and the names of some of our products, each providing different levels of protection. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

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, as further described in Part I, Item 1, "Business—Government Regulations" of this Annual Report. 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 of the EUA, including labeling and marketing requirements, which may be unclear and are subject to change. 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 supplement, or BLA or 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 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. For example, upon reviewing the performance of our Savanna RVP4+ assay against the clinical market's expectations, we withdrew our FDA 510(k) submission for this assay in March 2024 because the final dataset did not meet our expectations. 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 regulatory approvals, product recalls, seizure of products or injunctions against the distribution of our products, operating restrictions and criminal prosecution.

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 the distribution of our 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, sustainability 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 or does not comply with applicable regulations, 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 or claims that they do not comply with applicable regulations. Alleged manufacturing and design defects or regulatory non-compliance 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 laws and 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, HIPAA, the federal Physician Payments Sunshine Act, FDCA, 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 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-bribery and 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 EU, China, 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. Under China's Anti-Unfair Competition Law and Criminal Law regime, China has launched an intensified nationwide anti-corruption campaign in the healthcare sector, with strengthened enforcement actions and stricter regulations on both healthcare professionals and enterprises, which has delayed and could continue to delay the processing of public tenders or installations of certain of our instruments, which may have a negative impact on our commercial activities. 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 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 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 are also bound by contractual obligations with some of our customers relating to privacy, data protection and data security, some of which may be more stringent than applicable privacy, data security and data protection laws and regulations, as some companies 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 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 Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we do business have had an enhanced focus on issues related to the taxation of multinational corporations. These agencies are striving to define, legislate and enforce inappropriate "base erosion and profit shifting" by means of payments between affiliates in different taxing jurisdictions at disparate 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 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. 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 29, 2024, we had total indebtedness of $2,483.1 million, and we had availability under our Revolving Credit Facility of $589.0 million (net of $13.0 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 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). Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 10. 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 recent leadership transitions or activities of labor unions or works 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 $32.4 million as of December 29, 2024. 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 29, 2024, we had approximately 6,600 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 16% 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 identified material weaknesses in our internal control over financial reporting which, if not remediated appropriately or timely, could affect our ability to record, process and report financial information accurately, impair our ability to prepare financial statements, negatively affect investor confidence and cause reputational harm.

Effective internal controls are necessary for us to provide reliable and accurate financial reporting and financial statements for external purposes in accordance with GAAP. A failure to maintain effective internal control over financial reporting could lead to violations, unintentional or otherwise, of laws and regulations. As disclosed in Part II, Item 9A, "Controls and Procedures" of this Annual Report, as of December 29, 2024, we identified material weaknesses in our internal control over financial reporting relating to (i) ineffectively designed controls related to financial information generated from certain software solutions and design deficiencies over certain management review controls and (ii) insufficient controls over the evaluation of all available evidence to assess realizability of deferred tax assets. As a result, our management concluded that disclosure controls and procedures and internal control over financial reporting were not effective as of December 29, 2024. While we are actively engaged in the process of designing appropriate controls to address these material weaknesses, there can be no assurance that the actions will fully remediate the material weaknesses in a timely manner. If we are unable to remediate the material weaknesses, or are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected. Litigation, government investigations or regulatory enforcement actions arising out of any such failure or alleged failure could subject us to civil and criminal penalties that could materially and adversely affect our reputation, financial condition and operating results. The material weaknesses, remediation actions, and any related litigation, government investigations or regulatory enforcement actions will require management attention and resources and cause us to incur unanticipated costs, and could negatively affect investor confidence in our financial statements, cause us reputational harm and raise other risks to our operations.

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 sustainability 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 regulators, investors, customers, suppliers, vendors, employees and other stakeholders concerning corporate responsibility and sustainability in particular. Government entities are enhancing or advancing legal and regulatory requirements, including disclosure requirements, specific to sustainability matters. For example, the state of California has adopted new climate change disclosure requirements and the EU has adopted the Corporate Sustainability Reporting Directive. Compliance with such rules could require significant effort and resources and result in changes to our current sustainability goals. Additionally, many investors use sustainability factors to help guide their investment strategies and, in some cases, may choose not to invest in us if they believe our sustainability performance is inadequate. Moreover, a number of customers who are payors or distributors have adopted, or may adopt, procurement policies that include sustainability 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 sustainability 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 sustainability 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 sustainability metrics, including sustainability-related disclosures that may be required of public companies by regulators, stakeholders may conclude that our performance related to corporate responsibility and sustainability matters is inadequate.

Moreover, if our market capitalization increases, we may be benchmarked against larger peer companies, some of which may have more resources than us and thus may have achieved better sustainability performance and/or a higher sustainability rating profile. We may face reputational damage if our sustainability performance or sustainability 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 sustainability-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 comply with sustainability regulations or to satisfy stakeholder expectations related to our sustainability performance or to accomplish or accurately track and report on our sustainability initiatives or goals on a timely basis, or at all, could result in the loss of business, inability to sell our products in certain jurisdictions, 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.

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. As restrictions on resale end, 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.

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) robust controls across our 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 generally aligned with applicable cybersecurity regulations and informed in part by certain industry standards, principles and frameworks, such as those set by the National Institute of Standards and Technology. 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 on security controls of our products and manufacturing sites and 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. Components of our cybersecurity program are also evaluated by third parties such as our customers, external auditors and government agencies.

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 cybersecurity threats or incidents that have materially affected us since the beginning of the last fiscal year, there can be no guarantee that we will not be the subject of future successful attacks, threats or incidents that could materially affect us. 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 CISO, SGC and the Audit Committee. Our CISO is primarily responsible for our global information security program. In this role, the CISO is responsible for the effective operation of our 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 over 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 CEO; CFO; Chief Operations Officer; Chief Legal Officer; Vice President, Information Technology; 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) 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 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 Vice President, Information Technology, CISO, additional members of the SGC, and other personnel also annually 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 Vice President, Information Technology, and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. Properties

At December 29, 2024, our material operating locations, which we define as the facilities we lease with more than 75,000 square feet plus all owned facilities with 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 [(1)]	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	2027	89,114	Manufacturing
Pompano Beach, FL	Owned	N/A	21,500	Manufacturing

(1) In December 2024, the Company entered into an agreement for the expansion of the office building and manufacturing facility.

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 14. 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 19, 2025, we had approximately 84 common stockholders of record and we do not anticipate paying any cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

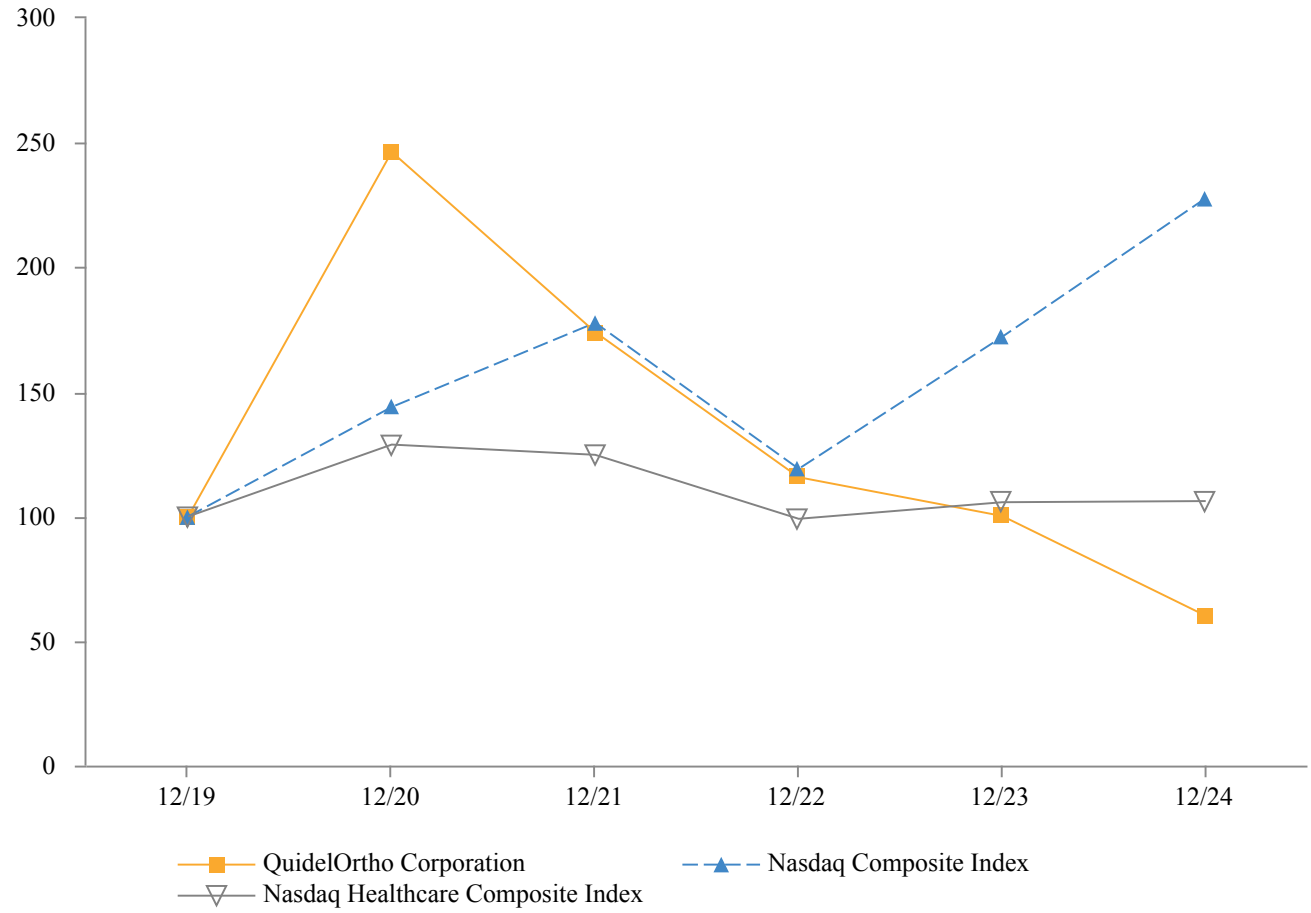
On August 17, 2022, our Board authorized the Stock Repurchase Program, allowing us to repurchase up to $300.0 million of our common stock, which expired on August 17, 2024. We did not repurchase any shares of our common stock in 2024 through the expiration date.

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 29, 2024. The graph assumes (i) an initial investment of $100 as of the market close on December 31, 2019 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 ended 2020 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



Company/Index	Base Period 12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
QuidelOrtho Corporation	**$ 100.00**	$ 246.34	$ 174.03	$ 115.76	$ 100.20	$ 60.16
Nasdaq Composite Index	**$ 100.00**	$ 143.95	$ 177.76	$ 119.14	$ 172.14	$ 227.78
Nasdaq Health Care Composite Index	**$ 100.00**	$ 128.87	$ 124.76	$ 99.07	$ 105.73	$ 106.19

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 25 of this Annual Report. In addition, our discussion of QuidelOrtho's financial condition

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

Overview

Our 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 support clarity for 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 and JPAC (Japan and Asia Pacific) are immaterial operating segments that are not considered reportable segments and are included in "Other." We generate our revenue in the following business units: Labs, Transfusion Medicine (Immunohematology and Donor Screening product categories), Point of Care and Molecular Diagnostics. We also generate non-core revenue, including through our contract manufacturing business and certain business collaborations, which accounted for $94.2 million, $125.0 million and $73.1 million for fiscal years ended 2024, 2023 and 2022, respectively.

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 fiscal years ended 2024 and 2023 each include a full year of Ortho operations. For additional information about the Combinations, refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 2. Business Combination."

For fiscal year ended 2024, Total revenues decreased by 7% to $2,782.9 million as compared to the prior year. For fiscal year ended 2023, Total revenues decreased by 8% to $2,997.8 million as compared to the prior year. These decreases were primarily driven by variability of our U.S. respiratory products. Currency exchange rates had an unfavorable impact of approximately 60 basis points and 100 basis points on our growth rates for fiscal years ended 2024 and 2023, respectively. Our revenues can be highly concentrated over a small number of products, including certain of our respiratory products. For fiscal years ended 2024, 2023 and 2022, revenues related to our respiratory products accounted for approximately 18%, 24% and 57% of our Total revenues, respectively.

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. 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. The winding down of the U.S. donor screening portfolio, as compared to prior years, contributed to the decline in revenue with a margin lower than our overall margin. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 4. Revenue" for more information. The wind-down of our U.S. donor screening portfolio is expected to be substantially complete by the end of 2025.

Supply Chains

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. While we encountered increasing pressures on raw material pricing during fiscal years ended 2023 and 2022, inflationary impacts during fiscal year ended 2024 lessened and returned closer to pre-COVID-19 pandemic levels. To help mitigate these supply chain challenges, we (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, (iii) create redundancy in our global supply chain and (iv) insource activity where it makes strategic and financial sense. In addition, we routinely evaluate our supply chain for potential gaps and continue to take other steps intended to help address continuity.

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 2024 compared to 2023 due to the decreased occurrence and duration of COVID-19 in an endemic environment and a COVID-19 government award in 2023 that

did not occur in 2024. We expect overall demand for our non-respiratory and 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 season, 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. We expect to continue to evaluate strategic opportunities to (i) expand our product lines and services, production capabilities, technologies and geographic footprint and address other business challenges and opportunities, and (ii) rationalize and consolidate facilities with the goal to improve our long-term results.

While we expect the revenues and financial results from our non-respiratory and respiratory products to be affected by the highly competitive environment and our respiratory products to be affected by the seasonal demands of the respiratory season, 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 2024, 2023 and 2022

Our fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. Fiscal years ended 2024, 2023 and 2022 were 52 weeks.

Revenues

The following table compares Total revenues by business unit for fiscal years ended 2024, 2023 and 2022:

	Fiscal Year Ended				
(Dollars in millions)	2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Labs	$ 1,426.7	$ 1,425.4	$ 820.2	— %	74 %
Immunohematology [(1)]	522.6	512.4	296.8	2 %	73 %
Donor Screening [(1)]	115.5	136.1	97.0	(15)%	40 %
Point of Care	694.1	892.2	1,955.3	(22)%	(54)%
Molecular Diagnostics	24.0	31.7	96.7	(24)%	(67)%
Total revenues	$ 2,782.9	$ 2,997.8	$ 3,266.0	(7)%	(8)%

(1) For presentation purposes, as a result of the wind-down of the U.S. donor screening portfolio, the previously reported Transfusion Medicine business unit is shown in its two product categories: Immunohematology and Donor Screening. Prior periods have been revised to align with the current period presentation.

For fiscal year ended 2024, Total revenues decreased to $2,782.9 million from $2,997.8 million for the prior year. The increase in Labs revenue was primarily related to growth in reagents, consumables and services, partially offset by decreased COVID-19 and non-core revenue compared to the prior year. Immunohematology revenue increased 2% compared to the prior year period, primarily due to reagent growth. Donor Screening revenue decreased 15% compared to the prior year period, primarily due to the wind-down of the U.S. donor screening business. The Point of Care business unit contributed to revenue decline, driven by a decrease of $188.6 million in sales of QuickVue SARS Antigen assays, primarily due to a COVID-19 government award in the prior year period, and a decrease of $5.8 million in sales of Sofia SARS Antigen assays. Molecular Diagnostics sales decreased by $7.7 million, primarily driven by lower demand. Currency exchange rates had an unfavorable impact of approximately 60 basis points on the growth rate for fiscal year ended 2024.

For fiscal year ended 2023, Total revenues decreased to $2,997.8 million from $3,266.0 million for the prior year. The increases in Labs, Immunohematology and Donor Screening 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 ended 2023.

Cost of Sales, Excluding Amortization of Intangible Assets

Cost of sales, excluding amortization of intangible assets, was $1,496.4 million, or 53.8% of Total revenues, for fiscal year ended 2024, compared to $1,500.7 million, or 50.1% of Total revenues, for fiscal year ended 2023. The increase in cost of sales, excluding amortization of intangible assets as a percentage of revenue, was driven primarily by product mix, partially offset by a prior year period COVID-19 government award, along with the corresponding inventory reserve release of $39 million.

Cost of sales, excluding amortization of intangible assets, increased to $1,500.7 million, or 50.1% of Total revenues, for fiscal year ended 2023, compared to $1,329.8 million, or 40.7% of Total revenues, for fiscal year ended 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, Immunohematology and Donor Screening 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 ended 2022.

Operating Expenses

The following table summarizes operating expenses for fiscal years ended 2024, 2023 and 2022:

	Fiscal Year Ended					
(Dollars in millions)	2024	% of Total Revenues	2023	% of Total Revenues	2022	% of Total Revenues
Selling, marketing and administrative	$ 766.8	27.6 %	$ 763.2	25.5 %	$ 621.0	19.0 %
Research and development	218.7	7.9 %	245.0	8.2 %	187.9	5.8 %
Amortization of intangible assets	203.4	7.3 %	204.8	6.8 %	132.5	4.1 %
Acquisition and integration costs	127.2	4.6 %	113.4	3.8 %	136.0	4.2 %
Goodwill impairment charge	1,822.6	N/M	—	N/M	—	N/M
Asset impairment charge	56.9	N/M	4.5	N/M	2.8	N/M
Other operating expenses	51.8	1.9 %	27.1	0.9 %	12.3	0.4 %

* N/M - Not meaningful

Selling, Marketing and Administrative Expenses

Selling, marketing and administrative expenses for fiscal year ended 2024 increased by $3.6 million, or 0.5%, to $766.8 million from $763.2 million for the prior year, primarily due to higher incentive-based employee compensation costs, partially offset by compensation costs related to cost-savings initiatives and lower advertising costs.

Selling, marketing and administrative expenses for fiscal year ended 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.

Research and Development Expense

Research and development expense for fiscal year ended 2024 decreased by $26.3 million, or 10.7%, to $218.7 million from $245.0 million for the prior year, primarily due to lower employee compensation costs and costs of outside services.

Research and development expense for fiscal year ended 2023 increased by $57.1 million, or 30.4%, to $245.0 million from $187.9 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.

Amortization of Intangible Assets

Amortization of intangible assets for fiscal years ended 2024, 2023 and 2022 was $203.4 million, $204.8 million and $132.5 million, respectively. The increase in amortization expense in fiscal year ended 2023 compared to fiscal year ended 2022 was primarily due to the Combinations.

Acquisition and Integration Costs

Acquisition and integration costs were $127.2 million, $113.4 million and $136.0 million for fiscal years ended 2024, 2023 and 2022, respectively. The increase in costs in fiscal year ended 2024 compared to fiscal year ended 2023 was primarily due to employee compensation related charges and consulting costs. The decrease in costs in fiscal year ended 2023 compared to fiscal

year ended 2022 was primarily due to acquisition costs attributable to the Combinations, partially offset by higher integration-related costs.

Goodwill Impairment Charge

During fiscal year ended 2024, we recognized a non-cash goodwill impairment charge of $1.8 billion. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 9. Goodwill and Intangible Assets, Net" for more information.

Asset Impairment Charge

During fiscal year ended 2024, we recognized an impairment charge of $56.9 million related to the long-lived assets classified as assets held for sale. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 8. Assets Held for Sale" for more information. Asset impairment charges were $4.5 million and $2.8 million for fiscal years ended 2023 and 2022, respectively.

Other Operating Expenses

Other operating expenses were $51.8 million, $27.1 million and $12.3 million for fiscal years ended 2024, 2023 and 2022, respectively, which were primarily related to the profit share expense for our Joint Business with Grifols and, in fiscal year ended 2024, a $20.0 million write off of the tax assessment refund. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 5. Segment and Geographic Information" for more information.

Non-operating Expenses

Interest Expense, Net

Interest expense, net was $163.5 million, $147.6 million and $75.7 million for fiscal years ended 2024, 2023 and 2022, respectively. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 10. Borrowings" for more information.

Loss on Extinguishment of Debt

Loss on extinguishment of debt was $24.0 million for fiscal year ended 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, Net

Other expense, net was $7.1 million, $20.6 million and $8.1 million for fiscal years ended 2024, 2023 and 2022, respectively. The decrease in Other expense, net in fiscal year ended 2024 compared to fiscal year ended 2023 was primarily related to (i) a prior year 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) Credit Agreement amendment fees, partially offset by loss on investments in the prior year period. The increase in Other expense, net in fiscal year ended 2023 compared to fiscal year ended 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. Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 6. Income Taxes" for more information.

Income Taxes

For fiscal years ended 2024 and 2023, we recognized income tax benefits of $79.5 million in relation to loss before taxes of $2,131.5 million and $19.0 million in relation to loss before taxes of $29.1 million, resulting in effective tax rates of 3.7% and 65.3%, respectively. For fiscal year ended 2024, the effective tax rate differed from the U.S. federal statutory rate primarily due to goodwill impairment charges that were nondeductible for tax purposes. For fiscal year ended 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.

We recognized an income tax benefit of $19.0 million, resulting in an effective tax rate of 65.3% for fiscal year ended 2023, compared to an income tax provision of $187.2 million, resulting in an effective tax rate of 25.4% for fiscal year ended 2022. For fiscal year ended 2022, the effective tax rate differed from the U.S. federal statutory rate, primarily due to 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.

Segment Results

We operate under three geographically-based reportable segments: North America, EMEA and China. Our operations in Latin America and JPAC (Japan and Asia Pacific) are immaterial operating segments that are not considered reportable segments and are included in "Other." In the fourth quarter of 2024, we revised the internal allocation of certain global costs primarily between the North America segment and Corporate to better align costs that impact us as a whole. Prior periods have been revised to align with the current period presentation.

The key indicators that we monitor are as follows:

- Total revenues — This measure is discussed in the section entitled "Results of Operations."
- Adjusted EBITDA — Adjusted EBITDA by reportable segment is used by our management to measure and evaluate the internal operating performance of our reportable segments. It is also the basis for calculating certain management incentive compensation programs. We believe that this measurement is useful to investors as a way to analyze the underlying trends in our core business, including at the segment level, consistently across the periods presented and to evaluate performance under management incentive compensation programs. Adjusted EBITDA consists of Net (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. Refer to 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)	2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Total revenues	$ 1,619.8	$ 1,877.1	$ 2,536.5	(14)%	(26)%
Adjusted EBITDA	$ 892.1	$ 1,025.2	$ 1,689.2	(13)%	(39)%

Total revenues were $1,619.8 million for fiscal year ended 2024, compared to $1,877.1 million for fiscal year ended 2023. The decrease was primarily driven by (i) a decrease in Point of Care revenue, primarily due to a COVID-19 government award in the prior year period, (ii) the wind-down of the U.S. donor screening business and (iii) the settlement award from a third party related to one of our collaboration agreements in the prior year period.

Total revenues were $1,877.1 million for fiscal year ended 2023, compared to $2,536.5 million for fiscal year ended 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.

Adjusted EBITDA was $892.1 million for fiscal year ended 2024, compared to $1,025.2 million for fiscal year ended 2023. The decrease was primarily driven by (i) a COVID-19 government award in the prior year period, along with the corresponding inventory reserve release of $39 million, (ii) the wind-down of the U.S. donor screening business and (iii) the settlement award from a third party related to one of our collaboration agreements in the prior year period, partially offset by a decrease in employee compensation costs and other operating expenses.

Adjusted EBITDA was $1,025.2 million for fiscal year ended 2023, compared to $1,689.2 million for fiscal year ended 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.

EMEA

Total revenues and Adjusted EBITDA for EMEA were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Total revenues	$ 335.8	$ 327.3	$ 206.8	3 %	58 %
Adjusted EBITDA	$ 46.5	$ 41.0	$ 31.4	13 %	31 %

Total revenues were $335.8 million for fiscal year ended 2024, compared to $327.3 million for fiscal year ended 2023. The increase was primarily driven by increases in Immunohematology and Point of Care revenues.

Total revenues were $327.3 million for fiscal year ended 2023, compared to $206.8 million for fiscal year ended 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.

Adjusted EBITDA was $46.5 million for fiscal year ended 2024, compared to $41.0 million for fiscal year ended 2023. The increase was primarily driven by increases in Immunohematology and Point of Care revenues.

Adjusted EBITDA was $41.0 million for fiscal year ended 2023, compared to $31.4 million for fiscal year ended 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.

China

Total revenues and Adjusted EBITDA for China were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Total revenues	$ 325.0	$ 310.1	$ 220.0	5 %	41 %
Adjusted EBITDA	$ 130.5	$ 127.2	$ 99.4	3 %	28 %

Total revenues were $325.0 million for fiscal year ended 2024, compared to $310.1 million for fiscal year ended 2023. The increase was primarily driven by an increase in Labs revenue, partially offset by a decrease in Point of Care revenue.

Total revenues were $310.1 million for fiscal year ended 2023, compared to $220.0 million for fiscal year ended 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.

Adjusted EBITDA was $130.5 million for fiscal year ended 2024, compared to $127.2 million for fiscal year ended 2023. The increase was primarily driven by an increase in Labs revenue, partially offset by a decrease in Point of Care revenue and the impact from changes in product mix.

Adjusted EBITDA was $127.2 million for fiscal year ended 2023, compared to $99.4 million for fiscal year ended 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.

Other

Total revenues and Adjusted EBITDA for Other were as follows:

	Fiscal Year Ended				
(Dollars in millions)	2024	2023	2022	% Change 2024 vs. 2023	% Change 2023 vs. 2022
Total revenues	$ 502.3	$ 483.3	$ 302.7	4 %	60 %
Adjusted EBITDA	$ 133.5	$ 115.3	$ 91.2	16 %	26 %

Total revenues were $502.3 million for fiscal year ended 2024, compared to $483.3 million for fiscal year ended 2023. The increase was primarily driven by an increase in Labs revenue, partially offset by a decrease in Point of Care revenue.

Total revenues were $483.3 million for fiscal year ended 2023, compared to $302.7 million for fiscal year ended 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.

Adjusted EBITDA was $133.5 million for fiscal year ended 2024, compared to $115.3 million for fiscal year ended 2023. The increase was primarily driven by an increase in Labs revenue and a decrease in operating expenses, partially offset by a decrease in Point of Care revenue.

Adjusted EBITDA was $115.3 million for fiscal year ended 2023, compared to $91.2 million for fiscal year ended 2022. The increase was primarily driven by approximately $37 million of incremental impact of the Combinations, partially offset by lower Point of Care revenue.

Liquidity and Capital Resources

As of December 29, 2024 and December 31, 2023, our principal sources of liquidity consisted of the following:

(Dollars in millions)	December 29, 2024	December 31, 2023
Cash and cash equivalents	$ 98.3	$ 118.9
Marketable securities, current	—	48.4
Marketable securities, non-current	—	7.4
Total cash, cash equivalents and marketable securities	$ 98.3	$ 174.7
Amount available to borrow under the Revolving Credit Facility	$ 589.0	$ 787.1
Working capital including cash and cash equivalents and marketable securities, current	$ 220.1	$ 476.7

As of December 29, 2024, we had $98.3 million in Cash and cash equivalents, a $20.6 million decrease from December 31, 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.

Debt Capitalization

Our Credit Agreement consists of a $2,750.0 million Term Loan and an $800.0 million Revolving Credit Facility. Availability under the Revolving Credit Facility, after deducting letters of credit of $13.0 million and $198.0 million borrowings outstanding, was $589.0 million as of December 29, 2024.

On April 25, 2024, we entered into Amendment No. 2 to the Credit Agreement, by and among us, the lenders party thereto, and Bank of America, N.A., as administrative agent. The amendment sets a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) for the applicable measurement period as of the last day of each fiscal quarter of (a) 4.50 to 1.00 on or prior to June 30, 2023, (b) 4.00 to 1.00 after June 30, 2023 and on or prior to June 30, 2024, (c) 4.25 to 1.00 after June 30, 2024 and on or prior to December 31, 2024, (d) 4.00 to 1.00 after December 31, 2024 and on or prior to June 30, 2025 and (e) 3.75 to 1.00 each fiscal quarter after June 30, 2025. The Credit Agreement contains a minimum Consolidated Interest Coverage Ratio (as defined in the Credit Agreement) of 3.00 to 1.00 as of the end of any fiscal quarter for the most recently completed four fiscal quarters. We were in compliance with the financial covenants as of December 29, 2024.

Receivables Purchase Agreement

On March 31, 2023, we entered into an amendment to our existing 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.

Stock Repurchases

On August 17, 2022, our Board authorized the Stock Repurchase Program, allowing us to repurchase up to $300.0 million of our common stock, which expired on August 17, 2024. We did not repurchase any shares of our common stock during fiscal year ended 2024 through the expiration date. For the fiscal year ended 2023, we repurchased 120,000 shares of outstanding common stock under the Stock Repurchase Program for approximately $7.2 million.

Capital Expenditures

Annual capital expenditures, including investments, net of proceeds from government assistance allocated to fixed assets, were approximately $195 million, $196 million and $123 million in fiscal years ended 2024, 2023 and 2022, 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)	**2024**	**2023**	**2022**
Net cash provided by operating activities	$ 83.0	$ 280.2	$ 885.3
Net cash used for investing activities	(149.9)	(187.6)	(1,644.2)
Net cash provided by (used for) financing activities	48.8	(265.8)	252.0
Effect of exchange rates on cash	(2.9)	(1.2)	(2.0)
Net decrease in cash, cash equivalents and restricted cash	$ (21.0)	$ (174.4)	$ (508.9)

Fiscal Year Ended December 29, 2024

Cash provided by operating activities was $83.0 million for fiscal year ended 2024, and reflected a net loss of $2,052.0 million and non-cash adjustments of $2,293.7 million, primarily associated with a goodwill impairment charge and change in deferred tax assets and liabilities, as well as depreciation and amortization, asset impairment charge and stock-based compensation expense. Cash provided by operating activities was also driven by $134.1 million of cash outflows for inventories.

Cash used for investing activities was $149.9 million for fiscal year ended 2024, and was primarily related to $195.1 million in purchases of property, equipment, investments and intangibles, partially offset by $9.3 million in net proceeds from the sale of the McKellar, San Diego, CA facility. We also purchased $7.2 million and sold $63.1 million of marketable securities during fiscal year ended 2024.

Cash provided by financing activities was $48.8 million for fiscal year ended 2024, and was primarily related to net proceeds from the Revolving Credit Facility of $198.0 million, partially offset by payments on long-term borrowings of $143.0 million.

Fiscal Year Ended December 31, 2023

Cash provided by operating activities was $280.2 million for fiscal year ended 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, change in deferred tax assets and liabilities 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 ended 2023, and was primarily related to $209.3 million in purchases of property, equipment, investments and intangibles and $13.5 million in proceeds from government assistance allocated to fixed assets. We also purchased $60.1 million and sold $78.3 million of marketable securities during fiscal year ended 2023.

Cash used for financing activities was $265.8 million for fiscal year ended 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 ended 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, change in deferred tax assets and liabilities, 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 other changes in working capital, including $116.9 million of cash outflows for inventories.

Cash used for investing activities was $1,644.2 million for fiscal year ended 2022, and was primarily related to the Combinations. We purchased $140.9 million of property, equipment, investments and intangibles and received $18.4 million in proceeds from government assistance allocated to fixed assets. We also purchased $63.7 million and sold $53.4 million of marketable securities during 2022. Refer to 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 ended 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.

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 ended 2024, we transferred $148.9 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 Ortho business and realize cross-selling revenue synergies;
- our ability to realize revenue growth from our new technologies and create innovative products in our markets;
- outstanding debt and covenant restrictions;
- our ability to leverage our operating expenses to realize operating profits as we grow revenue;
- competing technological and market developments; and
- our entry into strategic collaborations with other companies or acquisitions of other companies or technologies to enhance or complement our product and service offerings.

Contractual Obligations 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 10. Borrowings," "—Note 6. Income Taxes," "—Note 11. Leases" and "—Note 14. 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 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.

Allowance 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 $39.8 million of our rebate reserves at December 29, 2024.

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.

As a result of the identification of indicators of impairment during the first quarter of 2024, we performed an interim impairment test that resulted in a non-cash goodwill impairment charge of $1.7 billion for the North America reporting unit. For our annual evaluation for impairment of goodwill as of September 30, 2024, 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. We concluded that the China and JPAC reporting units' carrying values exceeded their respective estimated fair values. As a result, we recorded non-cash goodwill impairment charges of $17.3 million and $61.4 million in the fourth quarter of 2024 for the China and JPAC reporting units, respectively.

The estimated fair values of the EMEA and Latin America reporting units exceeded their respective 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) was approximately 8% and 45%, respectively. To evaluate the sensitivity of the fair value calculations used in the interim goodwill impairment test for the EMEA and Latin America reporting units, we applied a hypothetical 5% decrease to the fair value of each reporting unit and compared that hypothetical value to the reporting unit's carrying value. 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) was approximately 3% and 37% for the EMEA and Latin America reporting units, respectively.

Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 9. Goodwill and Intangible Assets, Net" for more information on the goodwill impairment recognized in 2024.

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 29, 2024, we had a valuation allowance of $142.4 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. Refer to 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, 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. 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 $3.6 million per year before considering the impact of derivative instruments.

We have interest rate swap contracts with a total notional value of $1.8 billion to hedge future interest rate exposures on variable rate debt, including the Revolving Credit Facility and Term Loan.

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 44% of our Total revenues for the fiscal year ended December 29, 2024, 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.

We have entered into foreign currency forward contracts to manage our 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 $1.4 billion as of December 29, 2024, with maturity dates through November 2025.

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 29, 2024, (Loss) income before income taxes would have increased by approximately $7.1 million in fiscal year ended 2024. Because the Company was in a net long (receivable) 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 gain 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 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.

Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 16. Derivative Instruments and Hedging Activities" for additional information related to such forward contracts.

Credit Risk

The use of derivative instruments exposes us to credit risk if the counterparty fails to perform when the fair value of a derivative instrument contract is positive. If the counterparty fails to perform, collateral is not required by any party whether derivatives

are in an asset or liability position. We have a policy of diversifying derivatives with counterparties to mitigate the overall risk of counterparty defaults.

Refer to Part II, Item 8, "Financial Statements and Supplementary Data—Note 16. Derivative Instruments and Hedging Activities" for additional information.

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 29, 2024 and December 31, 2023, the related consolidated statements of (loss) income, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 29, 2024, 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 29, 2024 and December 31, 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 29, 2024, 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 29, 2024, 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 27, 2025 expressed an adverse opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

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

Allowance 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 29, 2024, the Company recognized an allowance on accounts receivable of $39.8 million for 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 estimate is based upon a high volume of data including inputs from third-party sources. In addition, the allowance for contractual rebates involves 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

To test the allowance for contractual rebates, our audit procedures included, among others, a retrospective analysis of the allowance for contractual rebates compared to actual rebate claims received and performance of analytical procedures and sensitivity analyses over the Company's significant inputs. We tested the underlying data used in management's calculations for accuracy and completeness, which included inspection of source data supporting distributor inventory levels. We also evaluated rebate claims received after year end to assess the accrual as of the balance sheet date and the Company's estimates.

Goodwill impairment assessments

Description of the Matter

As of December 29, 2024, the Company's goodwill balance was $649.5 million. During the year ended December 29, 2024, the Company recognized goodwill impairments totaling $1,822.6 million. As described in Note 1 and Note 9 to the consolidated financial statements, the Company evaluates goodwill at the reporting unit level for impairment on an annual basis on the first day of the fourth quarter of the fiscal year, or whenever events or changes in circumstances occur that indicate that the fair value of a reporting unit is below its carrying amount. In performing both interim and annual goodwill impairment assessments, reporting unit fair values were estimated by management using a weighted discounted cash flow method and guideline public company method.

Auditing the Company's interim and annual goodwill impairment assessments involved significant auditor judgment due to the significant estimation uncertainty in determining the fair value of the reporting units. The assumptions with a significant level of subjectivity or complexity utilized in the impairment assessments included the revenue growth rates, EBITDA margins and discount rates.

How We Addressed the Matter in Our Audit

To test the estimated fair value of the Company's reporting units, our audit procedures included, among others, evaluating the significant assumptions discussed above and testing the underlying data used by the Company in its analysis. We performed sensitivity analyses of the significant assumptions to evaluate changes in fair value of the reporting units to determine if contrary evidence exists. We also assessed the historical accuracy of the Company's forecasts of financial results used in developing fair value estimates to assist in evaluating the reliability of the forecasts utilized in the estimate. In addition, with the support of our valuation specialist, we evaluated the Company's use of a weighted discounted cash flow method and guideline public company method and selection of the discount rates, which included comparing the discount rates used by the Company against discount rate ranges that were independently developed using publicly available market data for comparable entities. In addition, we tested the Company's reconciliation of the fair value of the reporting units to the market capitalization of the Company.

/s/ Ernst & Young LLP

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

San Diego, California

February 27, 2025

QUIDELORTHO CORPORATION

CONSOLIDATED BALANCE SHEETS

(In millions, except par value)

	December 29, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 98.3	$ 118.9
Marketable securities	—	48.4
Accounts receivable, net	282.4	303.3
Inventories	533.7	577.8
Prepaid expenses and other current assets	262.4	262.1
Assets held for sale	42.1	—
Total current assets	1,218.9	1,310.5
Property, plant and equipment, net	1,380.2	1,443.8
Marketable securities	—	7.4
Right-of-use assets	168.7	169.6
Goodwill	649.5	2,492.0
Intangible assets, net	2,735.6	2,934.3
Deferred tax assets	—	25.9
Other assets	270.7	179.6
Total assets	$ 6,423.6	$ 8,563.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 246.0	$ 294.8
Accrued payroll and related expenses	116.9	84.8
Income tax payable	5.4	11.1
Current portion of borrowings	341.8	139.8
Other current liabilities	288.7	303.3
Total current liabilities	998.8	833.8
Operating lease liabilities	167.2	172.8
Long-term borrowings	2,141.3	2,274.8
Deferred tax liabilities	76.5	192.2
Other liabilities	55.3	83.6
Total liabilities	3,439.1	3,557.2
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5.0 shares authorized; none issued or outstanding at December 29, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share; 126.2 shares authorized; 67.3 and 66.7 shares issued and outstanding at December 29, 2024 and December 31, 2023, respectively	0.1	0.1
Additional paid-in capital	2,884.8	2,848.0
Accumulated other comprehensive loss	(36.2)	(30.0)
Retained earnings	135.8	2,187.8
Total stockholders' equity	2,984.5	5,005.9
Total liabilities and stockholders' equity	$ 6,423.6	$ 8,563.1

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF (LOSS) INCOME

(In millions, except per share data)

	Fiscal Year Ended		
	2024	2023	2022
Total revenues	$ 2,782.9	$ 2,997.8	$ 3,266.0
Cost of sales, excluding amortization of intangibles	1,496.4	1,500.7	1,329.8
Selling, marketing and administrative	766.8	763.2	621.0
Research and development	218.7	245.0	187.9
Amortization of intangible assets	203.4	204.8	132.5
Acquisition and integration costs	127.2	113.4	136.0
Goodwill impairment charge	1,822.6	—	—
Asset impairment charge	56.9	4.5	2.8
Other operating expenses	51.8	27.1	12.3
Operating (loss) income	(1,960.9)	139.1	843.7
Interest expense, net	163.5	147.6	75.7
Loss on extinguishment of debt	—	—	24.0
Other expense, net	7.1	20.6	8.1
(Loss) income before income taxes	(2,131.5)	(29.1)	735.9
(Benefit from) provision for income taxes	(79.5)	(19.0)	187.2
Net (loss) income	$ (2,052.0)	$ (10.1)	$ 548.7
Basic (loss) earnings per share	$ (30.54)	$ (0.15)	$ 9.66
Diluted (loss) earnings per share	$ (30.54)	$ (0.15)	$ 9.56
Weighted-average shares outstanding - basic	67.2	66.8	56.8
Weighted-average shares outstanding - diluted	67.2	66.8	57.4

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(In millions)

	Fiscal Year Ended		
	2024	2023	2022
Net (loss) income	$ (2,052.0)	$ (10.1)	$ 548.7
Other comprehensive (loss) income			
Changes in cumulative translation adjustment, net of tax	(38.4)	50.4	(69.8)
Changes in unrealized gains (losses) from investments, net of tax	—	0.5	(0.4)
Changes from pension and other post-employment benefits, net of tax	2.8	(2.0)	0.7
Changes in unrealized gains (losses) from cash flow hedges, net of tax:			
Net unrealized gains on derivative instruments	52.1	12.6	6.7
Reclassification of net realized gains on derivative instruments included in net income	(22.7)	(23.9)	(5.2)
Total change in unrealized gains (losses) from cash flow hedges, net of tax	29.4	(11.3)	1.5
Comprehensive (loss) income	$ (2,058.2)	$ 27.5	$ 480.7

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In millions)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings	Total stockholders' equity
	Shares	Par				
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
Issuance of common stock under equity compensation plans	0.7	—	5.4	—	—	5.4
Stock-based compensation expense	—	—	41.0	—	—	41.0
Tax withholdings related to vesting of stock-based awards	(0.1)	—	(9.6)	—	—	(9.6)
Other comprehensive loss, net of tax	—	—	—	(6.2)	—	(6.2)
Net loss	—	—	—	—	(2,052.0)	(2,052.0)
Balance at December 29, 2024	67.3	$ 0.1	$ 2,884.8	$ (36.2)	$ 135.8	$ 2,984.5

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

	Fiscal Year Ended		
	2024	2023	2022
OPERATING ACTIVITIES:			
Net (loss) income	$ (2,052.0)	$ (10.1)	$ 548.7
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	453.4	457.2	283.6
Goodwill impairment charge	1,822.6	—	—
Asset impairment charge	56.9	4.5	2.8
Stock-based compensation expense	42.1	51.6	48.4
Change in deferred tax assets and liabilities	(99.3)	(11.6)	(44.0)
Net change in operating lease right-of-use assets and liabilities	(0.2)	—	18.4
Payment of accreted interest on contingent and deferred consideration	—	(9.7)	(10.4)
Loss on extinguishment of debt	—	—	24.0
Unwind inventory fair value adjustment	—	—	60.6
Asset write off	20.0	—	—
Other non-cash, net	(1.8)	(6.8)	6.4
Changes in assets and liabilities:			
Accounts receivable	5.4	160.0	150.2
Inventories	(134.1)	(211.6)	(116.9)
Prepaid expenses and other current and non-current assets	(9.5)	(26.9)	(26.2)
Accounts payable	(23.4)	3.0	23.5
Accrued payroll and related expenses	35.0	(53.9)	18.2
Income taxes payable	(9.5)	(59.6)	(26.8)
Other current and non-current liabilities	(22.6)	(5.9)	(75.2)
Net cash provided by operating activities	83.0	280.2	885.3
INVESTING ACTIVITIES			
Acquisitions of property, plant, equipment, investments and intangibles	(195.1)	(209.3)	(140.9)
Proceeds from held for sale asset, net of costs to sell	9.3	—	—
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
Purchases of marketable securities	(7.2)	(60.1)	(63.7)
Proceeds from sale of marketable securities	63.1	78.3	53.4
Other payments	(20.0)	(10.0)	—
Net cash used for investing activities	(149.9)	(187.6)	(1,644.2)
FINANCING ACTIVITIES			
Proceeds from issuance of common stock	5.0	11.6	26.4
Short-term borrowings, net	(1.6)	1.6	—
Revolving credit facility, net	198.0	—	—
Proceeds from long-term borrowings, net of debt issuance costs	—	—	2,734.5
Payments on long-term borrowings and extinguishment costs	(143.0)	(228.0)	(2,388.3)
Payments of tax withholdings related to vesting of stock-based awards	(9.6)	(13.5)	(8.6)
Repurchases of common stock	—	(7.2)	(74.3)
Principal payments of acquisition contingent consideration	—	—	(4.2)
Principal payments of deferred consideration	—	(30.3)	(33.5)
Net cash provided by (used for) financing activities	48.8	(265.8)	252.0
Effect of exchange rates on cash	(2.9)	(1.2)	(2.0)
Net decrease in cash, cash equivalents and restricted cash	(21.0)	(174.4)	(508.9)
Cash, cash equivalents and restricted cash at beginning of period	119.5	293.9	802.8
Cash, cash equivalents and restricted cash at end of period	$ 98.5	$ 119.5	$ 293.9

	Fiscal Year Ended		
	2024	2023	2022
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid during the period for interest	$ 177.5	$ 150.0	$ 95.1
Cash paid during the period for income taxes	$ 41.6	$ 86.6	$ 264.8
Purchase of property, equipment and intangibles by incurring current liabilities	$ 25.9	$ 40.6	$ 40.4
Transfer of instrument inventories to fixed assets	$ 148.9	$ 154.6	$ 73.7
Reduction of other current liabilities upon issuance of restricted share units	$ 0.3	$ 1.9	$ 4.6
Initial recognition of finance lease right-of-use asset and liability	$ 12.5	$ —	$ —

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 support clarity for 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 ended 2024, 2023 and 2022, the Company's fiscal years ended on December 29, 2024, December 31, 2023 and January 1, 2023, respectively. Fiscal years ended 2024, 2023 and 2022 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.

Reclassifications

Certain reclassifications have been made to prior periods amounts to conform to the current period presentation. Such amounts include a reclassification of $4.5 million and $2.8 million recognized for fiscal years ended 2023 and 2022, respectively, related to impairment of long-lived assets from (i) Cost of sales, excluding amortization of intangibles (excludes $2.7 million and $0.2 million for fiscal years ended 2023 and 2022, respectively), and (ii) Research and development (excludes $1.8 million and $2.6 million for fiscal years ended 2023 and 2022, respectively), to Asset impairment charge.

The reclassifications did not have an impact on the Company's previously reported Consolidated Balance Sheets, Consolidated Statements of Comprehensive (Loss) Income, Consolidated Statements of Stockholders' Equity or Consolidated Statements of Cash Flows.

Consolidation

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Cash and Cash Equivalents

The Company considers cash equivalents to be highly liquid investments with a maturity at the date of purchase of three months or less. They are carried at cost plus accrued interest, which approximates fair value because of the short-term maturity of these

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

Restricted Cash

Restricted cash primarily consists of funds reserved for legal requirements. Restricted cash balances are included in Other assets in the Consolidated Balance Sheets.

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 AOCI 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, 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 (refer to "—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 $99.6 million and $91.8 million at December 29, 2024 and December 31, 2023, 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 AOCI.

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.

Assets Held for Sale

The following criteria are considered before concluding assets are classified as held for sale: (i) management's commitment to a plan to sell, (ii) availability for immediate sale in its present condition, (iii) initiation of an active program to identify a buyer, (iv) probability of a completed sale within one year, (v) actively marketed for sale at a reasonable price in relation to its current fair value, and (vi) likelihood of significant changes to the plan will be made or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the net assets are presented separately in the balance sheet as held for sale at the lower of its carrying amount or fair value less costs to sell and is no longer depreciated or amortized while classified as held for sale. The Company assesses the fair value of a long-lived asset less any costs to sell at each reporting period and until the asset is no longer classified as held for sale.

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 CODM reviews the Company's performance and allocates resources based on five operating segments: North America, EMEA, China, Latin America and JPAC (Japan and Asia Pacific). North America, EMEA and China are the Company's reportable segments; Latin America and JPAC are immaterial operating segments that are not considered reportable segments and are included in "Other." Each of these five 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.

As a result of the identification of indicators of impairment during the first quarter of 2024, the Company performed an interim impairment test that resulted in a non-cash goodwill impairment charge of $1.7 billion for the North America reporting unit. For the annual impairment test as of the beginning of the fiscal fourth quarter, the Company bypassed the qualitative assessment and proceeded directly to the quantitative goodwill impairment test for all reporting units. The Company concluded that the China and JPAC reporting units' goodwill were impaired. As a result, the Company recorded non-cash goodwill impairment charges of $17.3 million and $61.4 million in the fourth quarter of 2024 for the China and JPAC reporting units, respectively. Refer to "—Note 9. Goodwill and Intangible Assets, Net" for further information.

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 year ended 2022, due to a lack of history on which to base an estimate of products to be returned from the retailers, the Company established a reserve based on an estimate of total inventory remaining at our retailers which was subject to return. During fiscal year ended 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 ended 2023. The impact from this change in estimate was 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 6% and 1%, respectively, of the Company's Total revenues for fiscal year ended 2024. Variable lease revenue and fixed lease revenue represented approximately 4% and 1%, respectively, of the Company's Total revenues for fiscal year ended 2023. Revenue allocated to the instrument was not material for fiscal year ended 2022.

Government Assistance

In connection with the Combinations, the Company acquired a previously established agreement between Ortho and 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 ended

2023 and 2022, respectively, which were recorded as reductions to the carrying value of the related assets. No funding was received during fiscal year ended 2024.

Research and Development Costs

R&D 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 R&D 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 $125.4 million, $124.1 million and $104.9 million for fiscal years ended 2024, 2023 and 2022, 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 $6.2 million, $15.1 million and $26.8 million for fiscal years ended 2024, 2023 and 2022, 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 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 (i) stock options and (ii) RSUs, which include time-based RSUs, performance-based RSUs and restricted stock awards, to employees and non-employee 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 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 (Loss) Income

Comprehensive (loss) 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

Recently Adopted Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, that is intended to improve the disclosures about reportable segments and add more detailed information about a reportable segment's expenses. The amendments in the ASU require public entities to disclose on an annual and interim basis (i) significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss, (ii) other segment items by reportable segment, (iii) the title and position of the CODM and (iv) an explanation of how the CODM uses the reported measures of segment profit or loss in assessing segment performance and deciding how to allocate resources. The ASU does not change the definition of a segment, the method for determining segments, the criteria for aggregating operating segments into reportable segments, or the current specifically enumerated segment expenses that are required to be disclosed. The ASU was adopted in the fourth quarter of 2024 and applied retrospectively to all prior periods presented (refer to "—Note 5. Segment and Geographic Information"). The adoption of this ASU did not impact the Company's results of operations, cash flows or financial condition.

Recently Issued Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to improve its income tax disclosure requirements. Under the guidance, entities must annually (i) disclose specific categories in the rate reconciliation and (ii) provide additional information for reconciling items that meet a quantitative threshold. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. Other than the respective disclosures, the ASU is not expected to have an impact to the Company's Consolidated Financial Statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40), which requires disclosure, in the notes to the financial statements, of specified information about certain costs and expenses. This ASU is effective for public entities for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Other than the respective disclosures, the ASU is not expected to have an impact to 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 stockholders 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 stockholders 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.

In 2023, the Company recognized measurement period adjustments to Goodwill of $19.9 million resulting from finalization of tax-related matters. 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)	Purchase Price Allocation
Cash and cash equivalents	$ 234.5
Accounts receivable	240.6
Inventories [1]	384.4
Property, plant and equipment	948.9
Goodwill	2,158.5
Intangible assets	3,168.0
Prepaid expenses and other assets	270.4
Total assets	7,405.3
Accounts payable	(135.0)
Accrued payroll and related expenses	(81.1)
Long-term borrowings, including current portion [2]	(2,268.4)
Deferred tax liability	(260.1)
Other current and non-current liabilities	(369.6)
Total liabilities	(3,114.2)
Total purchase consideration	$ 4,291.1

(1) 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 ended 2022.

(2) 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. Refer to "—Note 9. Goodwill and Intangible Assets, Net" for further information.

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 ended 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 ended 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 ended 2021 and the reclassification of loss on extinguishment of debt in fiscal years ended 2021 and 2022;
- the reclassification of expense related to the accelerated vesting of certain stock awards of Ortho's former CEO; 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 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)	2024	2023	2022
Basic weighted-average shares of common stock outstanding	67.2	66.8	56.8
Dilutive potential shares issuable from stock options and RSUs [(1)]	—	—	0.6
Diluted weighted-average shares of common stock outstanding	67.2	66.8	57.4

(1) In fiscal years ended 2024 and 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)	**2024**	**2023**
Basic weighted-average shares of common stock outstanding	67.2	66.8
Dilutive potential shares issuable from stock options and RSUs	0.2	0.5
Diluted weighted-average shares of common stock outstanding	67.4	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 under the treasury stock method. These stock options and RSUs represented 1.8 million, 1.6 million and 0.9 million shares of common stock for fiscal years ended 2024, 2023 and 2022, 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 29, 2024 and December 31, 2023 was $32.5 million and $46.2 million, respectively.

The contract asset balance consisted of the following components:

- 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 as of December 31, 2023. There was no contract asset remaining as of December 29, 2024;
- 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 $32.5 million and $41.8 million as of December 29, 2024 and December 31, 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 as of December 31, 2023. There was no contract asset remaining as of December 29, 2024.

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 ended 2024 and 2023.

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 $33.5 million and $36.8 million as of December 29, 2024 and December 31, 2023, respectively, and was included in Other current liabilities in the Consolidated Balance Sheets. 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 $17.3 million and $13.9 million as of December 29, 2024 and December 31, 2023, respectively, and was included in Other liabilities in the Consolidated Balance Sheets. The amount of deferred revenue as of December 31, 2023 that was recorded in Total revenues during fiscal year ended 2024 was $34.0 million. The amount of deferred revenue as of January 1, 2023 that was recorded in Total revenues during fiscal year ended 2023 was $72.1 million.

Joint Business with Grifols

The Company has an ongoing 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 $29.5 million, $47.3 million and $18.6 million during fiscal years ended 2024, 2023 and 2022, respectively. These amounts included the Company's portion of the pre-tax net profit of $21.1 million, $21.4 million and $11.1 million during fiscal years ended 2024, 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 $8.4 million, $26.0 million and $7.5 million during fiscal years ended 2024, 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)	2024	2023	2022
Labs	$ 1,426.7	$ 1,425.4	$ 820.2
Immunohematology [(1)]	522.6	512.4	296.8
Donor Screening [(1)]	115.5	136.1	97.0
Point of Care	694.1	892.2	1,955.3
Molecular Diagnostics	24.0	31.7	96.7
Total revenues	$ 2,782.9	$ 2,997.8	$ 3,266.0

(1) For presentation purposes, as a result of the wind-down of the U.S. donor screening portfolio, the previously reported Transfusion Medicine business unit is shown in its two product categories: Immunohematology and Donor Screening. Prior periods have been revised to align with the current period presentation.

Concentration of Revenue and Credit Risk

For fiscal year ended 2024, one customer represented 11% of Total revenues in the North America segment. For fiscal year ended 2023, no customer individually accounted for more than 10% of Total revenues. For fiscal year ended 2022, two separate customers accounted for 20% and 11% of Total revenues, in the Other and North America segments, respectively.

Revenue related to the Company's respiratory products accounted for 18%, 24% and 57% of Total revenues for fiscal years ended 2024, 2023 and 2022, respectively.

As of December 29, 2024 and December 31, 2023, customers with a balance due in excess of 10% of Accounts receivable, net totaled $33.7 million and $63.5 million, 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 and JPAC are immaterial operating segments that are not considered reportable segments and are included in "Other."

In the fourth quarter of 2024, the Company revised the internal allocation of certain global costs primarily between the North America segment and Corporate to better align costs that impact the Company as a whole. Prior periods have been revised to align with the current period presentation. The following table presents the results of operations of the Company's reportable segments for fiscal years ended 2024, 2023 and 2022:

	Fiscal Year Ended 2024				
(In millions)	North America	EMEA	China	Other	Total
Total revenues	$ 1,619.8	$ 335.8	$ 325.0	$ 502.3	$ 2,782.9
Less [1]:					
Cost of sales, excluding amortization of intangibles	547.0	179.5	148.0	271.3	1,145.8
Selling, marketing and administrative	179.6	105.8	44.6	96.6	426.6
Research and development	1.6	2.6	4.3	3.1	11.6
Other expense, net	(0.5)	1.4	(2.4)	(2.2)	(3.7)
Total segment Adjusted EBITDA	$ 892.1	$ 46.5	$ 130.5	$ 133.5	1,202.6
Reconciliation of segment Adjusted EBITDA					
Corporate [2]					(659.7)
Depreciation and amortization					(453.4)
Interest expense, net					(163.5)
Acquisition and integration costs					(127.2)
Goodwill impairment charge					(1,822.6)
Asset impairment charge					(56.9)
Asset write off [3]					(20.0)
Amortization of deferred cloud computing implementation costs					(14.7)
Employee compensation charges					(5.6)
Credit Agreement amendment fees					(4.0)
EU medical device regulation transition costs [4]					(2.0)
Loss on disposal [5]					(1.2)
Gain on investments					0.7
Other adjustments					(4.0)
(Loss) income before income taxes					$ (2,131.5)

	Fiscal Year Ended 2023				
(In millions)	North America	EMEA	China	Other	Total
Total revenues	$ 1,877.1	$ 327.3	$ 310.1	$ 483.3	$ 2,997.8
Less [1]:					
Cost of sales, excluding amortization of intangibles	644.3	176.2	134.9	264.7	1,220.1
Selling, marketing and administrative	205.9	105.1	44.7	100.1	455.8
Research and development	1.6	2.5	4.5	3.1	11.7
Other expense, net	0.1	2.5	(1.2)	0.1	1.5
Total segment Adjusted EBITDA	$ 1,025.2	$ 41.0	$ 127.2	$ 115.3	1,308.7
Reconciliation of segment Adjusted EBITDA					
Corporate [2]					(585.5)
Depreciation and amortization					(457.2)
Interest expense, net					(147.6)
Acquisition and integration costs					(113.4)
Asset impairment charge					(4.5)
Tax indemnification expense					(12.6)
Amortization of deferred cloud computing implementation costs					(9.2)
Loss on investments					(3.6)
EU medical device regulation transition costs [4]					(2.5)
Other adjustments					(1.7)
(Loss) income before income taxes					$ (29.1)

(In millions)	Fiscal Year Ended 2022				
	North America	EMEA	China	Other	Total
Total revenues	$ 2,536.5	$ 206.8	$ 220.0	$ 302.7	$ 3,266.0
Less [1]:					
Cost of sales, excluding amortization of intangibles	619.8	105.1	92.5	153.4	970.8
Selling, marketing and administrative	226.6	66.7	27.1	56.1	376.5
Research and development	1.0	2.2	2.4	1.7	7.3
Other expense, net	(0.1)	1.4	(1.4)	0.3	0.2
Total segment Adjusted EBITDA	$ 1,689.2	$ 31.4	$ 99.4	$ 91.2	1,911.2
Reconciliation of segment Adjusted EBITDA					
Corporate [2]					(580.2)
Depreciation and amortization					(283.6)
Interest expense, net					(75.7)
Loss on extinguishment of debt					(24.0)
Acquisition and integration costs					(136.0)
Asset impairment charge					(2.8)
Unwind inventory fair value adjustment					(60.6)
Loss on investments					(5.8)
Amortization of deferred cloud computing implementation costs					(5.4)
Employee compensation charges					(3.2)
EU medical device regulation transition costs [4]					(1.5)
Tax indemnification expense					(0.3)
Derivative mark-to-market gain					4.4
Other adjustments					(0.6)
(Loss) income before income taxes					$ 735.9

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.

(2) 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.

(3) Represents the write off of the tax assessment refund related to the Luxembourg net wealth tax, as the weight of available evidence indicated that it is not more likely than not that the position will be sustained during the pendency of an appeal.

(4) 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.

(5) Represents loss on disposal from the sale of the McKellar, San Diego, CA facility.

The Company's President and CEO is the Company's CODM. The CODM reviews the segment adjusted EBITDA results against the forecast to assess segment performance and determine how to allocate resources. The CODM does not review and is not provided 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 Ended		
(In millions)	December 29, 2024	December 31, 2023	2024	2023	2022
Domestic	$ 947.8	$ 1,024.5	$ 1,568.8	$ 1,829.4	$ 2,451.7
Foreign	432.4	419.3	1,214.1	1,168.4	814.3
Total	$ 1,380.2	$ 1,443.8	$ 2,782.9	$ 2,997.8	$ 3,266.0

Note 6. Income Taxes

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

	Fiscal Year Ended		
(In millions)	2024	2023	2022
Current:			
Federal	$ (1.1)	$ (49.3)	$ 162.2
State	4.9	(1.6)	48.8
Foreign	22.1	36.4	17.6
Total current provision (benefit)	25.9	(14.5)	228.6
Deferred:			
Federal	(130.5)	8.5	(31.9)
State	0.6	(3.6)	(9.3)
Foreign	24.5	(9.4)	(0.2)
Total deferred benefit	(105.4)	(4.5)	(41.4)
(Benefit from) provision for income taxes	$ (79.5)	$ (19.0)	$ 187.2

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

	Fiscal Year Ended		
(In millions)	2024	2023	2022
United States	$ (2,167.1)	$ (163.9)	$ 672.1
Foreign	35.6	134.8	63.8
(Loss) income before income taxes	$ (2,131.5)	$ (29.1)	$ 735.9

Significant components of the Company's deferred tax assets and deferred tax liabilities as of December 29, 2024 and December 31, 2023 are shown below:

(In millions)	December 29, 2024	December 31, 2023
Deferred tax assets:		
Lease liability	$ 46.2	$ 47.2
Allowance for returns and discounts	38.4	42.3
Inventory reserve	14.7	14.0
Stock-based compensation	9.7	15.8
Tax loss, interest expense and credit carryforwards	468.7	603.8
Research & development expenses	95.7	75.9
Employee related obligations	13.2	6.0
Other, net	—	10.8
Total deferred tax assets	686.6	815.8
Valuation allowance for deferred tax assets	(142.4)	(274.7)
Total deferred tax assets, net of valuation allowance	544.2	541.1
Deferred tax liabilities:		
Right-of-use assets	(38.9)	(38.9)
Intangible assets	(468.6)	(554.2)
Property, plant and equipment	(107.5)	(114.3)
Other, net	(5.7)	—
Total deferred tax liabilities	(620.7)	(707.4)
Net deferred tax liabilities	$ (76.5)	$ (166.3)

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. During the fiscal year ended 2024, the Company was no longer demonstrating positive worldwide cumulative pre-tax book income, driven primarily by the impairment of goodwill during 2024. Absent utilizing more subjective projections of future income, a portion of the Company's federal net operating loss and interest expense carryforwards, a portion of certain state net operating loss, interest expense and tax credit carryforwards, and deferred tax assets related to certain foreign subsidiaries were not more likely than not to be realized. Therefore, the Company established a valuation allowance during the fiscal year ended 2024 for those U.S. and foreign deferred tax assets not more likely than not to be utilized.

The valuation allowance of $142.4 million as of December 29, 2024 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 interest and loss carryforwards from operations in the U.S. federal and state jurisdictions as well as Luxembourg, tax credits in U.S. state jurisdictions, and foreign distributors deferred tax assets. The amount of the deferred tax assets considered realizable could be adjusted in future years based on changes in available positive and negative evidence. The Company's overall valuation allowance recorded on deferred tax assets decreased primarily due to certain Luxembourg tax loss carryforwards for which a reserve for unrecognized tax benefits was recorded during the fiscal year ended 2024.

As of December 29, 2024, the Company had U.S. federal NOL carryforwards of $856.8 million, of which $345.0 million are subject to expiration through 2037 and $511.8 million are not subject to expiration. In addition, the Company has state NOLs of approximately $623.1 million, which will expire in years 2025 through 2044. As of December 29, 2024, the Company had U.S. federal research credit carryforwards of $29.8 million and federal foreign tax credits of $2.2 million, which will begin to expire in 2034 and 2028, respectively. In addition, the Company had state research credits of $20.0 million and state business credit carryforwards of $25.6 million, of which none expire. As of December 29, 2024, the Company had $245.7 million of NOL carryforwards in certain non-U.S. jurisdictions, net of uncertain tax positions. Of these, $203.8 million have no expiration and the remaining $41.9 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 ended 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)	2024	2023	2022
Tax (benefit) expense at statutory tax rate	$ (447.6)	$ (6.1)	$ 154.5
State tax (benefit) expense, net of federal tax	(7.2)	(2.8)	29.3
Foreign income taxed at rates other than the applicable U.S. rate	10.3	(23.0)	(27.5)
Goodwill Impairment	316.2	—	—
Permanent differences	14.8	(4.3)	8.2
Federal and state research credits—current year	(5.1)	(10.3)	(7.3)
Stock-based compensation	6.2	1.5	1.5
Change in valuation allowance	31.3	10.4	26.2
Foreign Derived Intangible Income Deduction	—	—	(10.2)
Global Intangible Low-Taxed Income	0.1	20.1	3.8
Change in uncertain tax positions	(7.8)	(11.8)	—
Other	9.3	7.3	8.7
(Benefit from) provision for income taxes	$ (79.5)	$ (19.0)	$ 187.2

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)	2024	2023	2022
Beginning balance	$ 28.8	$ 40.0	$ 17.7
Increases related to current year tax positions	—	2.6	1.8
Increases (decreases) related to prior year tax positions	165.4	(0.1)	(0.6)
Increases due to current year acquisitions	—	—	27.8
Decreases due to settlements and expirations	(10.3)	(13.7)	(6.7)
Ending balance	$ 183.9	$ 28.8	$ 40.0

As of December 29, 2024, December 31, 2023 and January 1, 2023, the Company had unrecognized tax benefits of $183.9 million, $28.8 million, and $40.0 million, respectively, of which $16.3 million, $21.6 million and $28.3 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 $5.1 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 $1.6 million as of December 29, 2024 and $4.0 million as of December 31, 2023. The Company recognized net interest income of $2.4 million and $4.3 million for fiscal years ended 2024 and 2023, respectively, due to the reversals of prior year accrued interest; interest expense for fiscal year ended 2022 was approximately $0.3 million.

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 2020 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 ended 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 29, 2024, the remaining indemnification receivable from Johnson & Johnson totaled $3.2 million and is included as a component of Prepaid expenses and other current assets on the Consolidated Balance Sheet.

In 2024, the Company determined that an uncertain tax benefit was required to be established related to net operating loss and interest expense carryforwards associated with an on-going Luxembourg income tax audit for tax years 2017 through 2020. As such, Luxembourg net operating loss and interest expense carryforward deferred tax assets that were previously fully offset by a valuation allowance have been reduced by the amount of uncertain tax benefits recorded as a contra deferred tax asset. The Luxembourg income tax audit is not expected to be settled in the next 12 months.

The following table summarizes the changes to the valuation allowance for balances for fiscal years ended 2024, 2023 and 2022:

	Beginning Balance	Additions Due to Current Year Acquisitions	Additions Charged to (Benefit From) Provision for Income Taxes	Currency Translation/ Other[1]	Ending Balance
Deferred tax valuation allowance					
Fiscal year ended December 29, 2024	$ 274.7	—	31.3	(163.6)	$ 142.4
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

(1) The other decreases in valuation allowance during fiscal year ended 2024 related predominately to reserves for unrecognized tax benefits recorded on certain Luxembourg tax loss carryforwards during the period.

Note 7. Balance Sheet Account Details

Cash, Cash Equivalents and Restricted Cash

(In millions)	December 29, 2024	December 31, 2023
Cash and cash equivalents	$ 98.3	$ 118.9
Restricted cash included in Other assets	0.2	0.6
Cash, cash equivalents and restricted cash	$ 98.5	$ 119.5

Marketable Securities

The Company had no marketable securities outstanding as of December 29, 2024. The following table is a summary of marketable securities as of December 31, 2023:

	December 31, 2023		
(In millions)	Amortized Cost	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 38.1	$ (0.1)	$ 38.0
Corporate asset-backed securities	8.9	—	8.9
Agency bonds	1.5	—	1.5
Total marketable securities, current	48.5	(0.1)	48.4
Corporate bonds, non-current	4.5	—	4.5
Corporate asset-backed securities, non-current	0.9	—	0.9
Sovereign government bonds, non-current	2.0	—	2.0
Total marketable securities	$ 55.9	$ (0.1)	$ 55.8

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 29, 2024	December 31, 2023
Accounts receivable	$ 382.0	$ 395.1
Allowance for contract rebates and discounts	(85.3)	(77.2)
Allowance for doubtful accounts	(14.3)	(14.6)
Total accounts receivable, net	$ 282.4	$ 303.3

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 $39.8 million and $31.3 million at December 29, 2024 and December 31, 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 ended 2024, 2023 and 2022:

(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 29, 2024	$ 91.8	$ 486.2	$ (478.4)	$ 99.6
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

(1) Includes opening balance of $31.4 million related to the Combinations during fiscal year ended 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 29, 2024	December 31, 2023
Raw materials	$ 211.8	$ 212.7
Work-in-process (materials, labor and overhead)	90.6	92.3
Finished goods (materials, labor and overhead)	291.6	318.1
Total inventories	$ 594.0	$ 623.1
Inventories	$ 533.7	$ 577.8
Other assets [1]	60.3	45.3
Total inventories	$ 594.0	$ 623.1

(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 29, 2024	December 31, 2023
Income taxes and other tax receivables	$ 112.1	$ 104.7
Prepaid expenses	77.3	67.0
Contract assets	32.5	46.2
Other receivables	24.3	34.2
Derivatives	15.1	6.9
Other	1.1	3.1
Total prepaid expenses and other current assets	$ 262.4	$ 262.1

Property, Plant and Equipment, Net

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

(In millions)	December 29, 2024	December 31, 2023
Equipment, furniture and fixtures	$ 673.2	$ 595.2
Building and improvements	330.0	399.7
Customer leased instruments	728.1	602.0
Finance lease right-of-use asset	12.5	—
Land	11.7	34.7
Construction in progress	350.9	332.8
Total property, plant and equipment, gross	2,106.4	1,964.4
Less: accumulated depreciation and amortization	(726.2)	(520.6)
Total property, plant and equipment, net	$ 1,380.2	$ 1,443.8

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 $250.0 million, $252.4 million and $151.1 million for fiscal years ended 2024, 2023 and 2022, respectively.

Other Current Liabilities

Other current liabilities consisted of the following:

(In millions)	December 29, 2024	December 31, 2023
Accrued commissions, rebates and returns	$ 67.4	$ 63.8
Accrued interest	39.0	30.3
Deferred revenue	33.5	36.8
Operating lease liabilities	31.1	26.7
Accrued other taxes payable	20.9	17.9
Derivatives	4.0	12.1
Other	92.8	115.7
Total other current liabilities	$ 288.7	$ 303.3

Note 8. Assets Held for Sale

As part of the Company's cost-savings initiatives, the Company has been evaluating its real estate footprint with the goal to relocate and consolidate its operations to improve long-term results. As a result, the Company decided to (i) sell the McKellar, San Diego, CA facility and (ii) sell the Raritan, NJ facility with the intent to subsequently lease back the right to use the property. In the second quarter of 2024, the properties met the requirements for reclassification from property, plant and equipment, net to assets held for sale when it became probable that the properties would be sold within one year. The carrying

value of the assets was reduced to its estimated relative fair value less costs to sell, resulting in an impairment charge of $56.9 million that was included in Asset impairment charge. The McKellar, San Diego, CA facility was sold during the fourth quarter of 2024 for net cash proceeds of $9.3 million, resulting in a loss on disposal of $1.2 million. This loss was included in Other operating expenses. The Raritan, NJ facility continues to meet the criteria for held for sale.

Note 9. Goodwill and Intangible Assets, Net

Changes in goodwill were as follows:

(In millions)	North America	EMEA	China	Other	Total
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
Impairment charge	(1,743.9)	—	(17.3)	(61.4)	(1,822.6)
Foreign currency translation	—	(16.4)	(1.8)	(1.7)	(19.9)
Balance at December 29, 2024	$ —	$ 566.0	$ 66.6	$ 16.9	$ 649.5

(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 ended 2023 to increase goodwill and decrease AOCI 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 29, 2024			December 31, 2023		
Description	Weighted-average useful life (years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Purchased technology	14.7	$ 999.5	$ (249.6)	$ 749.9	$ 1,000.4	$ (184.3)	$ 816.1
Customer relationships	20.0	2,027.1	(366.8)	1,660.3	2,029.0	(259.5)	1,769.5
License agreements	6.7	3.1	(3.1)	—	3.1	(3.1)	—
Patent and trademark costs	14.7	401.3	(87.6)	313.7	401.6	(60.1)	341.5
Software development costs	5.4	22.7	(11.0)	11.7	15.5	(8.3)	7.2
Total intangible assets		$ 3,453.7	$ (718.1)	$ 2,735.6	$ 3,449.6	$ (515.3)	$ 2,934.3

Interim impairment assessment

During the first quarter of 2024, the Company concluded that (i) the sustained decline in the Company's stock price and market capitalization that occurred during the first quarter of 2024, (ii) the faster than expected decline in COVID-19 and flu markets, and (iii) the delay in the timing of expected commercialization for Savanna were triggering events requiring an interim goodwill impairment assessment for all reporting units.

Based on the Company's interim goodwill impairment assessment in the first quarter of 2024, the Company concluded that the North America reporting unit's carrying value exceeded its estimated fair value. As a result, the Company recorded a non-cash goodwill impairment charge of $1.7 billion in the first quarter of 2024 for the North America reporting unit, which represented a full impairment of the goodwill allocated to the North America reporting unit. The decline in the estimated fair value of the North America reporting unit and the resulting impairment were primarily driven by revised short-term and mid-term forecasts for revenue and EBITDA expectations in North America.

Annual impairment assessment

During the fourth quarter of 2024, the Company conducted its annual goodwill impairment test for all reporting units pursuant to its policy. 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.

Based on the Company's annual goodwill impairment assessment in the fourth quarter of 2024, the Company concluded that the China and JPAC reporting units' carrying values exceeded their respective estimated fair values. As a result, the Company

recorded non-cash goodwill impairment charges of $17.3 million and $61.4 million in the fourth quarter of 2024 for the China and JPAC reporting units, respectively, which represented a full impairment of the goodwill allocated to the JPAC reporting unit.

The estimated fair values of the EMEA and Latin America reporting units as of the annual impairment assessment date exceeded their respective carrying values. The excess of the estimated fair value over carrying value (expressed as a percentage of carrying value for the respective reporting unit) was approximately 8% and 45%, respectively. Due to the significant excess of fair value over carrying value of these reporting units, they are less sensitive to changes in forecast assumptions. To evaluate the sensitivity of the fair value calculations used in the interim goodwill impairment test for the EMEA and Latin America reporting units, the Company applied a hypothetical 5% decrease to the fair value of each reporting unit and compared that hypothetical value to the reporting unit's carrying value. 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) was approximately 3% and 37% for the EMEA and Latin America reporting units, respectively.

The quantitative goodwill impairment assessment for all reporting units consisted of a fair value calculation that combines an income approach, using a discounted cash flow method, and a market approach, using the guideline public company method. The quantitative goodwill impairment assessment requires the application of a number of significant assumptions, including estimates of future revenue growth rates, EBITDA margins, discount rates and market multiples. The projected future revenue growth rates and EBITDA margins, and the resulting projected cash flows are based on historical experience and internal annual operating plans reviewed by management, extrapolated over the forecast period. Discount rates are determined using a weighted average cost of capital adjusted for risk factors specific to the reporting units. Market multiples are based on the guideline public company method using comparable publicly traded company multiples of revenue and EBITDA for a group of benchmark companies.

The Company believes the assumptions that were used in the quantitative goodwill impairment assessment are reasonable and consistent with assumptions that would be used by other marketplace participants.

The Company also reviews long-lived assets, including intangible assets, for impairment when events or changes in circumstances indicate the carrying value of an asset group may not be recoverable. Given the indications of possible impairment that occurred during the first quarter and fourth quarter of 2024, the Company tested its North America long-lived asset group for recoverability and impairment as of March 31, 2024 and its China and JPAC long-lived asset groups for recoverability and impairment as of December 29, 2024. Recoverability of long-lived assets 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. The undiscounted cash flows for the North America, China and JPAC long-lived asset groups were above the carrying value and the Company determined that the long-lived asset groups were recoverable, and no impairment existed as of March 31, 2024 for North America and as of December 29, 2024 for China and JPAC.

Amortization expense related to the capitalized software costs was $2.7 million, $0.6 million and $0.9 million for fiscal years ended 2024, 2023 and 2022, respectively. Amortization expense (including capitalized software costs) was $203.4 million, $204.8 million and $132.5 million for fiscal years ended 2024, 2023 and 2022, respectively.

The expected future annual amortization expense of the Company's finite-lived intangible assets held as of December 29, 2024 is as follows:

(In millions)	
2025	$ 189.8
2026	189.1
2027	187.1
2028	181.8
2029	180.6

Note 10. Borrowings

The components of borrowings were as follows:

(In millions)	December 29, 2024	December 31, 2023
Term Loan	$ 2,282.7	$ 2,420.2
Revolving Credit Facility	198.0	—
Financing lease obligation	7.9	0.4
Other short-term borrowings	—	1.6
Other long-term borrowings	—	0.4
Unamortized deferred financing costs	(5.5)	(8.0)
Total borrowings	2,483.1	2,414.6
Less: current portion	(341.8)	(139.8)
Long-term borrowings	$ 2,141.3	$ 2,274.8

The Credit Agreement consists of a $2,750.0 million Term Loan and an $800.0 million Revolving Credit Facility. Availability under the Revolving Credit Facility, after deducting letters of credit of $13.0 million and $198.0 million borrowings outstanding, was $589.0 million as of December 29, 2024. 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. During the year ended December 29, 2024, the Company made $137.5 million in payments on the Term Loan.

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.

On April 25, 2024, the Company entered into Amendment No. 2 to the Credit Agreement, by and among the Company, the lenders party thereto, and Bank of America, N.A., as administrative agent. The amendment sets a maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) for the applicable measurement period as of the last day of each fiscal quarter of (a) 4.50 to 1.00 on or prior to June 30, 2023, (b) 4.00 to 1.00 after June 30, 2023 and on or prior to June 30, 2024, (c) 4.25 to 1.00 after June 30, 2024 and on or prior to December 31, 2024, (d) 4.00 to 1.00 after December 31, 2024 and on or prior to June 30, 2025 and (e) 3.75 to 1.00 each fiscal quarter after June 30, 2025. The Credit Agreement contains 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 29, 2024.

The following table provides the detailed amounts within Interest expense, net for fiscal years ended 2024, 2023 and 2022:

	Fiscal Year Ended		
(In millions)	2024	2023	2022
Term Loan	$ 171.9	$ 175.6	$ 73.0
Revolving Credit Facility	16.4	3.3	1.5
Amortization of deferred financing costs	3.2	3.3	2.1
Derivative instruments and other	(25.4)	(29.1)	0.4
Interest income	(2.6)	(5.5)	(1.3)
Interest expense, net	$ 163.5	$ 147.6	$ 75.7

The following table provides a schedule of required future repayments of all borrowings outstanding as of December 29, 2024:

(In millions)	
2025	$ 341.8
2026	173.5
2027	1,973.3
2028	—
2029	—
Total	$ 2,488.6

Note 11. 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 ended 2024, 2023 and 2022 was $40.4 million, $38.4 million and $26.4 million, respectively. Variable lease cost for fiscal years ended 2024, 2023 and 2022 was $13.2 million, $9.8 million and $5.6 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)	2024	2023	2022
Cash paid for amounts included in the measurement of operating lease liabilities	$ 38.9	$ 36.5	$ 25.2
ROU assets obtained in exchange for new lease liabilities [1]	$ 30.5	$ 17.9	$ 29.9

(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 ended 2024 were as follows:

(In millions)	
2025	$ 38.8
2026	34.2
2027	28.5
2028	26.6
2029	22.5
Thereafter	80.3
Total lease payments	230.9
Less: imputed interest	(32.6)
Total	198.3
Less: current portion	(31.1)
Non-current portion	$ 167.2

Weighted average remaining lease term	7.7 years
Weighted average discount rate	4 %

Note 12. 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 ended 2024, 2023 or 2022.

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 (i) stock options and (ii) RSUs, which include time-based RSUs, performance-based RSUs and restricted stock awards, 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 and RSUs 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 29, 2024, 411,892 shares of common stock remained available for grant and 2,892,702 shares of common stock were reserved for future issuance under the 2018 Plan.

RSUs

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

For fiscal years ended 2024, 2023 and 2022, the Company granted 1.2 million, 0.6 million and 0.7 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 ended 2024, 2023 and 2022, RSUs were granted to certain non-employee directors of the Board in lieu of cash compensation as a part of the Company's Board Deferred Compensation Plan. The compensation expense associated with these RSU grants was $0.6 million, $0.5 million and $0.6 million for fiscal years ended 2024, 2023 and 2022, respectively.

Employee Deferred Compensation Plan

For fiscal years ended 2024, 2023 and 2022, certain employees of the Company were eligible to participate in the Employee Deferred Compensation Plan 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, certain 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 29, 2024, 538,401 shares of common stock remained available for future issuance.

Stock Repurchase Program

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, which expired on August 17, 2024.

During fiscal year ended 2024, the Company did not repurchase any shares of its common stock through the expiration date. During fiscal years ended 2023 and 2022, 120,000 and 953,468 shares of outstanding common stock, respectively, were repurchased under the Stock Repurchase Program.

Note 13. Stock-based Compensation

Stock-based compensation expense was as follows:

	Fiscal Year Ended		
(In millions)	2024	2023	2022
Cost of sales, excluding amortization of intangibles	$ 5.5	$ 4.3	$ 2.9
Selling, marketing and administrative	26.0	37.7	27.4
Research and development	3.4	4.9	4.9
Acquisition and integration costs	7.5	16.9	30.4
Total stock-based compensation expense	$ 42.4	$ 63.8	$ 65.6
Income tax (expense) benefit	$ (7.1)	$ 1.7	$ 2.1

The table above includes $12.2 million and $17.2 million of compensation expense related to liability-classified awards for fiscal years ended 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 ended 2023 and 2022, respectively. Amounts related to fiscal year ended 2024 were not material.

For fiscal years ended 2024, 2023 and 2022, the Company recorded $0.6 million, $1.5 million and $3.7 million in stock-based compensation expense, respectively, associated with the Employee Deferred Compensation Plan described in "—Note 12. Stockholders' Equity."

Stock Options

A summary of the status of stock option activity for fiscal year ended 2024 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 December 31, 2023	1,636	$ 89.69		
Granted	219	42.27		
Exercised	(106)	21.18		
Cancellations	(650)	89.04		
Outstanding at December 29, 2024	1,099	$ 87.22	5.61	$ 3,484
Vested and expected to vest at December 29, 2024	1,084	$ 87.71	5.56	$ 3,427
Exercisable at December 29, 2024	815	$ 96.24	4.50	$ 2,598

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 29, 2024	December 31, 2023	January 1, 2023
Risk-free interest rate	4.60 %	3.52 %	1.96 %
Expected option life (in years)	5.69	5.53	4.80
Volatility rate	59 %	57 %	57 %
Dividend rate	0 %	0 %	0 %
Weighted-average grant date fair value	$24.37	$48.17	$50.62

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 $2.1 million, $4.4 million and $13.7 million for options exercised during fiscal years ended 2024, 2023 and 2022, 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 ended 2023.

As of December 29, 2024, total unrecognized compensation expense related to stock options was approximately $6.3 million and the related weighted-average period over which it is expected to be recognized is approximately 1.8 years. The maximum contractual term of the Company's stock options is ten years.

RSUs

A summary of the status of RSU activity for fiscal year ended 2024 is as follows:

(In thousands, except price data)	Shares	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2023	1,156	$ 95.56
Granted	1,240	50.05
Vested	(522)	94.55
Forfeited	(492)	83.45
Non-vested at December 29, 2024	1,382	$ 59.42

The total amount of unrecognized compensation expense related to non-vested RSUs as of December 29, 2024 was approximately $53.4 million, which is expected to be recognized over a weighted-average period of approximately 1.8 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 December 31, 2023 and January 1, 2023 was $86.49 and $97.31, respectively.

Note 14. Commitments and Contingencies

Purchase Obligations

The Company had $277.3 million of purchase obligations as of December 29, 2024, 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

On April 12, 2024, a purported stockholder of the Company filed a putative class action complaint under the federal securities laws against the Company and three of its current and former executives. The complaint, which is captioned Bristol County Retirement System v. QuidelOrtho Corporation, et al., Case No. 1:24-cv-02804-JAV (S.D.N.Y.) (the "Bristol County Complaint"), asserts claims for violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to statements regarding sales of the Company's COVID-19 diagnostic tests and the 510(k) submission for its Savanna RVP4 assay. The Bristol County Complaint seeks a judgment determining that the lawsuit can be maintained as a class action and awarding the plaintiff and putative class damages, pre- and post-judgment interest, attorneys' and experts' fees, and costs. On December 16, 2024, the court appointed Central States, Southeast and Southwest Areas Health and Welfare Fund and Teamsters Local 710 Pension Fund ("Teamsters Funds") as lead plaintiffs in the action, and approved their selection of lead counsel. Teamsters Funds filed an amended complaint on February 7, 2025, and added as additional defendants three current and former executives of the Company not previously named in the Bristol County Complaint.

On April 25, 2024, and June 21, 2024, two purported stockholders of the Company filed separate stockholder derivative complaints, purportedly on behalf of the Company, against the current and certain former members of the Board and three of the Company's current and former executives. The complaints, which are captioned Matthew Whitfield v. Kenneth F. Buechler, Ph.D., et al., Case No. 1:24-cv-03176-JAV (S.D.N.Y.) (the "Whitfield Complaint"), and Steven Pinkney v. Douglas Bryant, et al., Case No. 1:24-cv-4753-JAV (S.D.N.Y.) (the "Pinkney Complaint"), assert claims for violations of Sections 10(b), 14(a), and 20(a) of the Exchange Act and Rules 10b-5 and 14a-9 promulgated thereunder, breach of fiduciary duty, aiding and abetting breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets related to statements regarding sales of the Company's COVID-19 diagnostic tests and the 510(k) submission for its Savanna RVP4 assay. The Whitfield and Pinkney Complaints seek judgments awarding compensatory and punitive damages against the individual defendants, directing an accounting by the individual defendants, directing the Company and the individual defendants to take actions to improve the Company's governance and procedures, and awarding the costs and disbursements of the action, including attorneys' fees, accountants' and experts' fees, costs, and expenses. On December 16, 2024, the court consolidated the Whitfield and Pinkney Complaints into a single action and stayed the consolidated derivative action.

The Company disputes the allegations of wrongdoing and intends to defend itself vigorously in these matters. Nevertheless, the outcomes of these lawsuits are uncertain and cannot be predicted with any certainty. Accordingly, at this time, the Company is not able to estimate a possible loss or range of loss that may result from these lawsuits or to determine whether such loss, if any, would have a material adverse effect on its business, financial condition, results of operations or liquidity.

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 current legal actions to which the Company is able to estimate a possible loss or range of loss, 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 $18.5 million, $21.8 million and $7.9 million for fiscal years ended 2024, 2023 and 2022, respectively.

Note 15. 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 29, 2024				December 31, 2023			
(In millions)	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Marketable securities	$ —	$ —	$ —	$ —	$ —	$ 55.8	$ —	$ 55.8
Derivative assets	—	36.6	—	36.6	—	6.9	—	6.9
Total assets measured at fair value	$ —	$ 36.6	$ —	$ 36.6	$ —	$ 62.7	$ —	$ 62.7
Liabilities:								
Derivative liabilities	$ —	$ 5.4	$ —	$ 5.4	$ —	$ 27.5	$ —	$ 27.5
Contingent consideration	—	—	—	—	—	—	0.1	0.1
Total liabilities measured at fair value	$ —	$ 5.4	$ —	$ 5.4	$ —	$ 27.5	$ 0.1	$ 27.6

There were no transfers of assets or liabilities into or out of Level 3 of the fair value hierarchy during fiscal years ended 2024 and 2023.

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 $2,254.2 million at December 29, 2024, compared to the carrying amount, excluding debt issuance costs, of $2,282.7 million. 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 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 16. 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. Refer to "—Note 10. 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 $6.5 million as of December 29, 2024 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 29, 2024, 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 ended 2022, the Company recognized an immaterial gain within Other expense, 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, Czech Koruna, Danish Krone, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Philippine Peso, Singapore Dollar, South Korean Won, Swedish Krona, Swiss Franc 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. Pre-tax unrealized gain of $8.4 million as of December 29, 2024 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, net.

The following table provides details of the currency hedging instruments outstanding as of December 29, 2024:

Description	Notional Amount (In millions)	Hedge Designation
Foreign currency forward contracts	$ 630.1	Cash Flow Hedge
Foreign currency forward contracts	$ 764.0	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 29, 2024, 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 29, 2024			
Foreign currency forward contracts (sales)	$ (13.0)	Total revenues	$ 2.5
Foreign currency forward contracts (purchases)	$ 0.7	Cost of sales, excluding amortization of intangibles	$ 0.3
Interest rate derivatives	$ (44.8)	Interest expense, net	$ (25.5)
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)

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 exchange contracts are designated as hedges of the net investment in foreign operations. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustments 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:

	Net Investment Hedging Relationships	
(In millions)	Amount of Pre-tax Loss (Gain) Recognized in OCI	Amount of Pre-tax (Gain) Loss Recognized in Other Expense, Net for Amounts Excluded from Effectiveness Testing
Fiscal Year Ended December 29, 2024		
Foreign exchange contracts	$ (29.6)	$ (11.6)
Fiscal Year Ended December 31, 2023		
Foreign exchange contracts	$ 8.5	$ (1.0)

Fair value gains on foreign currency forward contracts, as determined using Level 2 inputs, that do not qualify for hedge accounting treatment are recorded in Other expense, net and were $12.4 million for fiscal year ended 2024. Fair value gains and losses on foreign currency forward contracts that do not qualify for hedge accounting treatment were not material for fiscal years ended 2023 and 2022.

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, net and were $3.4 million for fiscal year ended 2022. There were no fair value gains and losses on interest rate derivatives that do not qualify for hedge accounting treatment for fiscal years ended 2024 and 2023.

The following table summarizes the fair value of designated and non-designated hedging instruments recognized within the Consolidated Balance Sheets as of December 29, 2024 and December 31, 2023:

(In millions)	December 29, 2024	December 31, 2023
Designated cash flow hedges		
Interest rate derivatives:		
Prepaid expenses and other current assets	$ 1.3	$ 0.2
Other assets	12.4	—
Other liabilities	—	6.9
Foreign currency forward contracts:		
Prepaid expenses and other current assets	11.0	3.2
Other assets	9.1	—
Other current liabilities	3.3	9.4
Other liabilities	1.4	8.5
Non-designated hedging instruments		
Foreign currency forward contracts:		
Prepaid expenses and other current assets	2.8	3.5
Other current liabilities	0.7	2.7

Note 17. 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 29, 2024 and December 31, 2023. The following tables set forth the changes to the PBO and plan assets:

(In millions)	Fiscal Year Ended December 29, 2024	Fiscal Year Ended December 31, 2023
Defined Benefit Plans		
Change in benefit obligation:		
PBO at beginning of year	$ 36.9	$ 33.9
Service cost	2.1	2.0
Interest cost	1.1	1.0
Contributions by plan participants	0.1	—
Benefits paid	(1.3)	(0.2)
Actuarial (gain) loss	(1.4)	2.8
Settlements	(1.8)	(2.4)
Foreign currency exchange rate changes	(2.7)	(0.2)
PBO at end of year	$ 33.0	$ 36.9
Change in plan assets:		
Fair value of plan assets at beginning of year	$ 20.4	$ 20.6
Actual return on plan assets	1.0	1.1
Employer contributions	2.6	2.1
Benefits paid	(1.0)	(0.2)
Settlements	(1.9)	(2.4)
Foreign currency exchange rate changes	(1.8)	(0.8)
Fair value of plan assets at end of year	$ 19.3	$ 20.4
Funded status at end of year	$ (13.7)	$ (16.5)
Amounts recognized on the Consolidated Balance Sheets:		
Other assets	$ 1.3	$ 0.7
Other current liabilities	(0.4)	(0.4)
Other liabilities	(14.6)	(16.8)
Net amount recognized	$ (13.7)	$ (16.5)

(In millions)	Fiscal Year Ended December 29, 2024	Fiscal Year Ended December 31, 2023
Other Post-employment Benefits		
Change in benefit obligation:		
PBO at beginning of year	$ 18.5	$ 18.6
Service cost	0.4	0.4
Interest cost	0.8	0.9
Benefits paid	(1.3)	(1.1)
Actuarial gain	(1.0)	(0.3)
PBO at end of year	$ 17.4	$ 18.5
Amounts recognized on the Consolidated Balance Sheets:		
Other current liabilities	$ (3.8)	$ (3.9)
Other liabilities	(13.6)	(14.6)
Net amount recognized	$ (17.4)	$ (18.5)

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 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 29, 2024 and December 31, 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 29, 2024	December 31, 2023
ABO	$ 26.3	$ 29.3
Plans with PBO in excess of plan assets		
PBO	$ 20.7	$ 22.2
Fair value of plan assets	6.1	5.7
Plans with ABO in excess of plan assets		
PBO	$ 18.6	$ 20.4
ABO	16.2	17.6
Fair value of plan assets	4.2	4.0

The pre-tax amounts that are not yet reflected in the net periodic benefit cost and are included in AOCI as of December 29, 2024 and December 31, 2023 include the following:

	Fiscal Year Ended	
(In millions)	December 29, 2024	December 31, 2023
Defined Benefit Plans		
Accumulated net actuarial losses	$ (0.5)	$ (2.3)
Accumulated prior service credit	$ 0.1	$ 0.1
Other Post-employment Benefits		
Accumulated net actuarial gains	$ 1.9	$ 0.9

These accumulated net actuarial gains and 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 $2.8 million and $2.5 million for the fiscal years ended December 29, 2024 and December 31, 2023, respectively, and was primarily related to service cost. Changes in plan assets and benefit obligations recognized in other comprehensive (loss) income were $(1.8) million and $2.1 million for the fiscal years ended December 29, 2024 and December 31, 2023, respectively.

Net periodic benefit cost for the Company's other post-employment benefit plans was $1.2 million and $1.3 million for the fiscal years ended December 29, 2024 and December 31, 2023, respectively, and was primarily related to interest cost. Changes in benefit obligations recognized in other comprehensive (loss) income were $(1.0) million for the fiscal year ended December 29, 2024 and were not material for fiscal year ended December 31, 2023.

The components of net periodic benefit cost other than the service cost component are recorded in Other expense, 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 29, 2024	December 31, 2023
Defined Benefit Plans		
Weighted average discount rate	3.3 %	3.3 %
Weighted average rate of compensation increases	3.3 %	3.2 %
Other Post-employment Benefits		
Weighted average discount rate	5.0 %	4.8 %

The critical assumptions used in determining the net periodic benefit cost for fiscal years ended 2024 and 2023 are as follows:

	December 29, 2024	December 31, 2023
Defined Benefit Plans		
Weighted average discount rate	3.3 %	3.1 %
Weighted average expected rate of compensation increases	3.2 %	3.0 %
Weighted average expected return on plan assets	2.9 %	2.5 %
Other Post-employment Benefits		
Weighted average discount rate	4.8 %	5.5 %

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 29, 2024
Health care cost trend rate assumed for next year - Pre-65	5.80 %
Health care cost trend rate assumed for next year - Post-65	5.63 %
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, the Company's 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 29, 2024, the Company expects to contribute $2.0 million to defined benefit plans in fiscal year 2025.

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
2025	$ 1.7	$ 3.8
2026	1.3	3.1
2027	2.2	2.6
2028	1.8	1.9
2029	2.0	1.5
2030-2034	13.3	5.6

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 29, 2024 and December 31, 2023.

	Fair Value Measurements at December 29, 2024			
(In millions)	Total	Level 1	Level 2	Level 3
U.S. equity securities	$ 2.2	$ 2.2	$ —	$ —
Japan equity securities	3.0	3.0	—	—
Other international equity securities	0.9	0.9	—	—
U.S. government bonds	0.5	0.5	—	—
Japan government bonds	1.2	1.2	—	—
Other international government bonds	1.8	1.8	—	—
Cash and cash equivalents	3.6	3.6	—	—
Insurance contracts	6.1	—	—	6.1
Total	$ 19.3	$ 13.2	$ —	$ 6.1

	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

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 are 46% for debt securities, 51% for equity securities and 3% for other assets.

The table below presents a roll-forward of activity for the Level 3 assets for fiscal years ended 2024 and 2023:

(In millions)	Level 3 Assets
Balance at January 1, 2023	$ 6.1
Transfers out	(1.0)
Net purchases and settlements	0.6
Balance at December 31, 2023	$ 5.7
Net purchases and settlements	0.4
Balance at December 29, 2024	$ 6.1

Defined Contribution Plans

The Company offers defined contribution plans to eligible employees primarily in the U.S., whereby employees contribute a portion of their compensation. Company matching and other Company contributions are also provided to the plans. Once

Company matching contributions have been paid, the Company has no further payment obligations. The Company's contributions for its employees totaled approximately $23.6 million, $18.6 million and $15.1 million for fiscal years ended 2024, 2023 and 2022, respectively, which are recognized as expense as incurred in the Consolidated Statements of (Loss) Income.

Note 18. Accumulated Other Comprehensive Loss

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

(In millions)	Foreign Currency Translation Adjustments	Available-for-Sale Investments	Pension and Other Post-employment Benefits	Cash Flow Hedges	Accumulated Other Comprehensive Income (Loss)
Balance at January 2, 2022	$ 0.5	$ (0.1)	$ —	$ —	$ 0.4
Current period deferrals [1]	(69.8)	(0.4)	0.7	6.7	(62.8)
Amounts reclassified to Net (loss) income	—	—	—	(5.2)	(5.2)
Net change	(69.8)	(0.4)	0.7	1.5	(68.0)
Balance at January 1, 2023	$ (69.3)	$ (0.5)	$ 0.7	$ 1.5	$ (67.6)
Current period deferrals [1]	51.4	0.5	(2.0)	12.6	62.5
Amounts reclassified to Net (loss) income	(1.0)	—	—	(23.9)	(24.9)
Net change	50.4	0.5	(2.0)	(11.3)	37.6
Balance at December 31, 2023	$ (18.9)	$ —	$ (1.3)	$ (9.8)	$ (30.0)
Current period deferrals [1]	(26.8)	—	2.8	52.1	28.1
Amounts reclassified to Net (loss) income	(11.6)	—	—	(22.7)	(34.3)
Net change	(38.4)	—	2.8	29.4	(6.2)
Balance at December 29, 2024	$ (57.3)	$ —	$ 1.5	$ 19.6	$ (36.2)

(1) Includes tax impact of (i) $5.0 million, $3.7 million and $0.1 million related to cash flow hedges for fiscal years ended 2024, 2023 and 2022, respectively, and (ii) $4.2 million and $2.1 million related to foreign currency translation adjustments for fiscal years ended 2024 and 2023, respectively.

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 CEO and 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 not effective at a reasonable assurance level as of December 29, 2024 due to the material weaknesses described below in Management's Report on 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). Under the supervision and with the participation of management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation, our management concluded that our internal control over financial reporting was not effective as of December 29, 2024.

A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statement will not be prevented or detected on a timely basis.

As of December 29, 2024, the Company identified material weaknesses relating to:

(1) Undue reliance on information generated from certain software solutions affecting net revenue without effectively designed controls to ensure that the information generated from these software solutions used by management in accounting for gross revenue, accounts receivable and in the estimation of accrued rebates, was complete and accurate. We also determined there were design deficiencies over certain management review controls including lack of evidence of review and failure to consider the completeness and accuracy of information used in the performance of those controls related to these same accounts.

(2) Insufficient controls over the evaluation of all available evidence, both positive and negative, to assess realizability of deferred tax assets.

The effectiveness of our internal control over financial reporting as of December 29, 2024 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included herein, which contains an adverse opinion on the effectiveness of our internal control over financial reporting.

Remediation Plan: With respect to the material weaknesses above, management, under the oversight of the Audit Committee, is in the process of designing appropriate controls to address these material weaknesses. While we have taken steps to implement our remediation plan, the material weaknesses will not be considered remediated until the enhanced controls operate for a sufficient period of time and management has concluded, through testing, that the related controls are effective. The Company will monitor the effectiveness of its remediation plan and refine its remediation plan as appropriate.

Changes in internal control over financial reporting: There were no changes in our internal control over financial reporting during the fiscal quarter ended December 29, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than the remediation activities described herein.

During the period ended December 29, 2024, the Company identified an interim material weakness relating to the design and operating effectiveness of management's review controls over certain key assumptions that were utilized to determine fair value of reporting units in the Company's interim goodwill impairment assessment conducted in the first quarter of 2024. The Company enhanced the design and operation of certain management review controls operating over key assumptions, including projected financial information, by defining the precision by which the controls operate and retaining sufficient evidence of the review over key inputs and assumptions. In the fourth quarter of 2024, the Company conducted its annual goodwill impairment assessment for all reporting units and concluded that the interim material weakness was fully remediated as of December 29, 2024.

Prior to filing this Annual Report, we completed significant additional procedures for the year ended December 29, 2024. Based on these procedures, management believes that our Consolidated Financial Statements included in this Annual Report have been prepared in accordance with U.S. GAAP. Our CEO and CFO have certified, that based on their knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this Annual Report.

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 29, 2024, 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, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, QuidelOrtho Corporation (the Company) has not maintained effective internal control over financial reporting as of December 29, 2024, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

The Company identified a material weakness related to revenue, accounts receivable and accrued rebates due to undue reliance on information generated from certain software solutions and design and operating deficiencies related to management review controls. The Company also identified a material weakness related to insufficient controls over the evaluation of all available evidence to assess realizability of deferred tax assets.

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 29, 2024 and December 31, 2023, the related consolidated statements of (loss) income, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 29, 2024 and the related notes. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2024 consolidated financial statements, and this report does not affect our report dated February 27, 2025, which 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 27, 2025

Item 9B. Other Information

(a) On February 12, 2025, the Company furnished a Current Report on Form 8-K that attached a press release announcing unaudited financial results for its fourth quarter and full year ended December 29, 2024, and posted a supplemental earnings presentation setting forth such results on the investor relations portion of the Company's website (collectively, the "Earnings Materials"). Subsequent to the date of furnishing the Earnings Materials, in connection with the audit of our Consolidated Financial Statements by our independent registered public accounting firm and the assessment of realizability of deferred tax assets, we identified certain tax adjustments impacting the fourth quarter and full year of 2024, resulting in an increase in Provision for income taxes and a decrease in deferred tax assets, as well as conforming changes to other measures related to these adjustments (the "Adjustments"). This Annual Report updates the following for the fourth quarter and full year ended December 29, 2024:

Consolidated Statements of Operations

(in millions, except per share data)	Previously Reported in Earnings Release	Adjustments	Fourth Quarter Financial Results	Previously Reported in Earnings Release	Adjustments	Full Year Financial Results
Provision for (benefit from) income taxes	$ 12.5	$ 25.0	$ 37.5	$ (104.5)	$ 25.0	$ (79.5)
Net (loss) income	$ (153.4)	$ (25.0)	$ (178.4)	$ (2,027.0)	$ (25.0)	$ (2,052.0)
Basic (loss) earnings per share	$ (2.28)	$ (0.37)	$ (2.65)	$ (30.16)	$ (0.38)	$ (30.54)
Diluted (loss) earnings per share	$ (2.28)	$ (0.37)	$ (2.65)	$ (30.16)	$ (0.38)	$ (30.54)

Condensed Consolidated Balance Sheets

(in millions)	Previously Reported in Earnings Release	Adjustments	As of December 29, 2024
Deferred tax assets	$ 25.0	$ (25.0)	$ —
Total assets	$ 6,448.6	$ (25.0)	$ 6,423.6
Total stockholders' equity	$ 3,009.5	$ (25.0)	$ 2,984.5
Total liabilities and stockholders' equity	$ 6,448.6	$ (25.0)	$ 6,423.6

We have also updated the corresponding earnings release and earnings presentation on the investor relations portion of our website at https://ir.quidelortho.com to reflect these Adjustments, including related updates to the (i) Reconciliation of Non-GAAP Financial Information – Adjusted Net Income table and (ii) Reconciliation of Non-GAAP Financial Information – Adjusted EBITDA table. The Adjustments have no impact on the Condensed Consolidated Statements of Cash Flows, Adjusted EBITDA, Adjusted Net Income and Adjusted Diluted EPS for the fourth quarter and full year ended December 29, 2024 that were initially set forth in the earnings release and earnings presentation on February 12, 2025.

(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 2025 definitive proxy statement to be filed with the SEC within 120 days of the fiscal year ended December 29, 2024 (the "2025 Proxy Statement"), including under the headings "Proposal One - Election of Directors Proposal," "Corporate Governance," "Insider Trading Policy," "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 2025 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 2025 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 2025 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 2025 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 Annual Report:

(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+	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)

Exhibit Number	Description
10.2	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)
10.3	Amendment No. 2 to the Credit Agreement, dated April 25, 2024, by and among QuidelOrtho Corporation, the lenders party thereto, and Bank of America, N.A., as Administrative Agent (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on April 29, 2024)
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 Offer Letter, dated April 30, 2024, between QuidelOrtho Corporation and Brian J. Blaser (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 7, 2024)
10.13(1)	Certain compensation arrangements between QuidelOrtho Corporation and Joseph M. Busky (incorporated by reference to Item 5.02 of the Registrant's Form 8-K/A filed on February 29, 2024)
10.14(1)	Certain compensation arrangements between QuidelOrtho Corporation and Joseph M. Busky (incorporated by reference to Item 5.02 of the Registrant's Form 8-K filed on November 18, 2024)
10.15(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)
10.16(1)	Form of Integration and Retention Bonus Letter (incorporated by reference to Exhibit 10.4 to the Registrant's Form 8-K filed on February 4, 2022)
10.17(1)	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.10 to the Registrant's Form 8-K filed on May 27, 2022)
10.18(1)*	Form of Severance and Change in Control Agreement
10.19(1)	QuidelOrtho Board Deferred Compensation Plan (incorporated by reference to Exhibit 10.19 to the Registrant's Form 10-K for the fiscal year ended December 31, 2023 filed on February 29, 2024)
10.20(1)	QuidelOrtho Employee Deferred Compensation Plan (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the fiscal year ended December 31, 2023 filed on February 29, 2024)
10.21(1)	Form of Retention Compensation Agreement for Joseph M. Busky (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q for quarter ended June 30, 2024 filed on August 1, 2024)
10.22	Summers Ridge Lease (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 9, 2018)
10.23	Master Agreement, dated as of July 24, 2021, by and among Quidel Corporation, Quidel Cardiovascular, Inc., and Beckman Coulter, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on July 26, 2021)

Exhibit Number	Description
19.1*	QuidelOrtho Insider Trading Compliance Policy
21.1*	Subsidiaries of QuidelOrtho Corporation
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification by Principal Executive Officer of QuidelOrtho Corporation pursuant to Rules 13a-14(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 29, 2024, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of (Loss) Income, (iii) Consolidated Statements of Comprehensive (Loss) 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 29, 2024, 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.

SUMMARY OF ABBREVIATED TERMS

QuidelOrtho Corporation and its consolidated subsidiaries may be referred to as QuidelOrtho, the Company, we, our or us in this Annual Report, unless the context otherwise indicates. Throughout this Annual Report, we have used terms which are defined below:

ABO	Accumulated benefit obligation
Annual Report	Annual Report on Form 10-K for the fiscal year ended December 29, 2024
AOCI	Accumulated other comprehensive loss
ASC	Accounting Standards Codification
ASU	Accounting Standards Update
Audit Committee	Audit Committee of the Board
BARDA	Biomedical Advanced Research and Development Authority
BCA	Business Combination Agreement entered into as of December 22, 2021, by and among Quidel, Ortho, QuidelOrtho (formerly Coronado Topco, Inc.), Orca Holdco, Inc., Laguna Merger Sub, Inc., and Orca Holdco 2, Inc.
BLA	Biologics License Application
Board	Board of directors
CAT	Column agglutination technology
CCPA	California Privacy Rights Act of 2020
CEO	Chief Executive Officer

CFO	Chief Financial Officer
cGMPs	Current good manufacturing practices
CIIOs	Critical information infrastructure
CISO	Chief Information Security Officer
CLIA	The FDA's Clinical Laboratory Improvement Amendment of 1988
CMS	Centers for Medicare & Medicaid Services
CODM	Chief Operating Decision Maker
Combinations	Business combination consummated by Quidel and Ortho on May 27, 2022, pursuant to the BCA
Credit Agreement	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
CRL	Complete Response Letter
EBITDA	Earnings before interest, taxes, depreciation and amortization
EEA	European Economic Area
EMEA	Europe, the Middle East and Africa
EPS	(Loss) earnings per share
ESG	Environmental, social and governance
EU	European Union
EU IVDR	EU In Vitro Diagnostic Regulation (EU 2017/746)
EU MDR	EU Medical Device Regulation (EU 2017/745)
EUA	Emergency use authorization
Exchange Act	Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
FCA	False Claims Act
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	U.S. Federal Food, Drug, and Cosmetic Act
Financing	The Term Loan together with the Revolving Credit Facility
FTC	Federal Trade Commission
GAAP	Generally accepted accounting principles in the U.S.
GDPR	General Data Protection Regulation 2016/679
Grifols	Grifols Diagnostic Solutions, Inc.
Grifols Agreement	Agreement governing the Company's ongoing Joint Business between Ortho and Grifols, originally entered into in 1989 with a 50-year term, as amended
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
IND	Investigational New Drug Application
IPR&D	In-process research and development
ISO	International Organization for Standardization
IT	Information technology
IVD	In vitro diagnostics
Joint Business	Ongoing collaboration arrangement between Ortho and Grifols
JPAC	Japan and Asia Pacific
MACRA	The Medicare Access and CHIP Reauthorization Act of 2015
MDSAP	Medical Device Single Audit Program

NMPA	China's National Medical Products Administration, formerly CFDA
NOL	Net operating loss
OCI	Other comprehensive (loss) income
Ortho	Ortho Clinical Diagnostics Holdings plc
OTC	Over-the-counter
PAMA	Protecting Access to Medicare Act of 2014
PBO	Projected benefit obligations
PCR	Polymerase chain reaction
PHI	Protected health information
PIPEDA	Canada's Personal Information Protection and Electronic Documents Act
PIPL	China's Personal Information Protection Law
PMA	Premarket approval
POC	Point-of-care
POL	Physician office laboratory
PPACA	The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act
QMS	Quality Management System
QSR	Quality System Regulation
Quidel	Quidel Corporation
R&D	Research and development
RPA	Receivables purchase agreement, as amended on March 31, 2023, by and among Ortho-Clinical Diagnostics US FinanceCo I, LLC, as Seller, our wholly owned receivables financing subsidiary, Wells Fargo Bank, N.A., as administrative agent, Ortho-Clinical Diagnostics, Inc., as the Master Servicer and as an Originator, Quidel Corporation, as an Originator, and certain Purchasers
Revolving Credit Facility	$800.0 million revolving credit facility under the Credit Agreement
ROU	Right-of-use
RSUs	Restricted stock units; includes time-based RSUs, performance-based RSUs and restricted stock awards
RSV	Respiratory syncytial virus
SCCs	Standard contractual clauses
SEC	Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
SGC	Security Governance Committee
SOFR	Secured overnight financing rate
Stock Repurchase Program	A stock repurchase program allowing the Company to repurchase up to $300.0 million of its common stock through August 17, 2024, which was authorized by our Board of Directors on August 17, 2022
Term Loan	$2,750.0 million senior secured term loan facility under the Credit Agreement
U.K.	United Kingdom
U.K. IDTA	U.K. International Data Transfer Agreement
U.S.	United States
USD	United States dollar
VIP	ORTHO VERSEIA® Integrated Processor

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/ BRIAN J. BLASER

Brian J. Blaser
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2025

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/ BRIAN J. BLASER Brian J. Blaser	Chief Executive Officer (Principal Executive Officer)	February 27, 2025
/s/ JOSEPH M. BUSKY Joseph M. Busky	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2025
/s/ KENNETH F. BUECHLER Kenneth F. Buechler	Chairman of the Board	February 27, 2025
/s/ JOHN R. CHIMINSKI John R. Chiminski	Director	February 27, 2025
/s/ EVELYN S. DILSAVER Evelyn S. Dilsaver	Director	February 27, 2025
/s/ RICHARD S. HUENNEKENS Richard S. Huennekens	Director	February 27, 2025
/s/ EDWARD L. MICHAEL Edward L. Michael	Director	February 27, 2025
/s/ MARY LAKE POLAN Mary Lake Polan	Director	February 27, 2025
/s/ ANN D. RHOADS Ann D. Rhoads	Director	February 27, 2025
/s/ MATTHEW W. STROBECK Matthew W. Strobeck	Director	February 27, 2025
/s/ KENNETH J. WIDDER Kenneth J. Widder	Director	February 27, 2025
/s/ JOSEPH D. WILKINS JR. Joseph D. Wilkins Jr.	Director	February 27, 2025

Board of Directors

Kenneth F. Buechler, Ph.D.
Chairman of QuidelOrtho Corporation
Co-founder and Former President and Chief Scientific Officer of Biosite, Inc.

Brian J. Blaser
President and Chief Executive Officer of QuidelOrtho Corporation

John R. Chiminski
Former Chairman, President and Chief Executive Officer of Catalent, Inc.

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

R. Scott Huennekens
Former Chairman, President and Chief Executive Officer of Verb Surgical, Inc.

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

Mary Lake Polan, M.D., Ph.D., M.P.H.
Professor of Clinical Obstetrics, Gynecology and Reproductive Sciences, Yale University School of Medicine

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

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

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

Joseph D. Wilkins Jr.
Senior Advisor for THEO Transformation Advisory and Former Executive at Atlantic Health System, Quest Diagnostics and Danaher-Beckman Coulter

Executive Leadership

Brian J. Blaser
President and Chief Executive Officer

Lee Bowman
Chief Human Resources Officer

Joseph M. Busky
Chief Financial Officer

Michelle A. Hodges
Chief Legal Officer and Secretary

Philip D. McLellan
Chief Operations Officer

Jonathan P. Siegrist, Ph.D.
Executive Vice President of Research and Development and Chief Technology Officer

Corporate Information

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

Transfer Agent & Registrar
Computershare, Inc.
Website: www.computershare.com
Telephone inquiries: 1-800-736-3001 (U.S.)
1-781-575-3100 (International)
Email inquiries: web.queries@computershare.com

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

Form 10-K and Form 10-Q
Copies of QuidelOrtho’s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other reports that QuidelOrtho files with the Securities and Exchange Commission are available without charge upon request. Please contact Investor Relations.

Investor Relations
9975 Summers Ridge Road
San Diego, California 92121 USA
IR@QuidelOrtho.com

QuidelOrtho™

9975 Summers Ridge Road
San Diego, CA 92121 USA

800-874-1517
quidelortho.com

New QuidelOrtho branding may not be available in all markets, subject to country-specific regulatory approval.