UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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)	(zip code)

(858) 552-1100

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 30, 2024, 67,256,717 shares of the registrant's common stock were outstanding.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDELORTHO CORPORATION

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In millions, except par value)

	September 29, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 143.7	$ 118.9
Marketable securities	—	48.4
Accounts receivable, net	294.9	303.3
Inventories	577.0	577.8
Prepaid expenses and other current assets	344.2	262.1
Assets held for sale	52.8	—
Total current assets	1,412.6	1,310.5
Property, plant and equipment, net	1,363.9	1,443.8
Marketable securities	—	7.4
Right-of-use assets	175.3	169.6
Goodwill	770.6	2,492.0
Intangible assets, net	2,795.9	2,934.3
Deferred tax assets	25.7	25.9
Other assets	257.1	179.6
Total assets	$ 6,801.1	$ 8,563.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 247.2	$ 294.8
Accrued payroll and related expenses	113.0	84.8
Income tax payable	1.9	11.1
Current portion of borrowings	373.8	139.8
Other current liabilities	291.4	303.3
Total current liabilities	1,027.3	833.8
Operating lease liabilities	174.0	172.8
Long-term borrowings	2,176.6	2,274.8
Deferred tax liability	117.2	192.2
Other liabilities	119.3	83.6
Total liabilities	3,614.4	3,557.2
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5.0 shares authorized; none issued or outstanding at September 29, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share; 126.2 shares authorized; 67.2 and 66.7 shares issued and outstanding at September 29, 2024 and December 31, 2023, respectively	0.1	0.1
Additional paid-in capital	2,875.9	2,848.0
Accumulated other comprehensive loss	(3.5)	(30.0)
Retained earnings	314.2	2,187.8
Total stockholders' equity	3,186.7	5,005.9
Total liabilities and stockholders' equity	$ 6,801.1	$ 8,563.1

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF LOSS

(Unaudited)

(In millions, except per share data)

	Three Months Ended		Nine Months Ended	
	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Total revenues	$ 727.1	$ 744.0	$ 2,075.1	$ 2,255.2
Cost of sales, excluding amortization of intangibles	374.8	374.6	1,114.7	1,140.7
Selling, marketing and administrative	186.4	194.1	579.3	575.6
Research and development	55.9	61.5	171.4	185.7
Amortization of intangible assets	51.9	51.4	155.5	153.6
Integration related costs	36.8	26.5	90.3	80.4
Goodwill impairment charge	—	—	1,743.9	—
Asset impairment charge	—	2.2	56.9	3.2
Other operating expenses	6.3	7.4	23.6	17.0
Operating income (loss)	15.0	26.3	(1,860.5)	99.0
Interest expense, net	42.9	37.7	122.9	110.9
Other expense, net	0.9	4.1	7.2	8.0
Loss before income taxes	(28.8)	(15.5)	(1,990.6)	(19.9)
Benefit from income taxes	(8.9)	(2.8)	(117.0)	(2.8)
Net loss	$ (19.9)	$ (12.7)	$ (1,873.6)	$ (17.1)
Basic loss per share	$ (0.30)	$ (0.19)	$ (27.92)	$ (0.26)
Diluted loss per share	$ (0.30)	$ (0.19)	$ (27.92)	$ (0.26)
Weighted-average shares outstanding - basic	67.3	66.9	67.1	66.8
Weighted-average shares outstanding - diluted	67.3	66.9	67.1	66.8

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(In millions)

	Three Months Ended		Nine Months Ended	
	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Net loss	$ (19.9)	$ (12.7)	$ (1,873.6)	$ (17.1)
Other comprehensive income (loss)				
Changes in cumulative translation adjustment, net of tax	61.6	(55.3)	35.5	(17.2)
Changes in unrealized gains from investments, net of tax	—	0.2	—	0.3
Changes in unrealized (losses) gains from cash flow hedges, net of tax:				
Net unrealized (losses) gains on derivative instruments	(33.7)	24.5	9.9	47.6
Reclassification of net realized gains on derivative instruments included in net income	(6.8)	(6.3)	(18.9)	(16.3)
Total change in unrealized (losses) gains from cash flow hedges, net of tax	(40.5)	18.2	(9.0)	31.3
Comprehensive income (loss)	$ 1.2	$ (49.6)	$ (1,847.1)	$ (2.7)

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

(In millions)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
	Shares	Par				
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	0.2	—	0.8	—	—	0.8
Stock-based compensation expense	—	—	9.0	—	—	9.0
Tax withholdings related to vesting of stock-based awards	(0.1)	—	(5.8)	—	—	(5.8)
Other comprehensive income, net of tax	—	—	—	3.8	—	3.8
Net loss	—	—	—	—	(1,706.0)	(1,706.0)
Balance at March 31, 2024	66.8	0.1	2,852.0	(26.2)	481.8	3,307.7
Issuance of common stock under equity compensation plans	0.4	—	4.1	—	—	4.1
Stock-based compensation expense	—	—	10.3	—	—	10.3
Tax withholdings related to vesting of stock-based awards	(0.1)	—	(2.5)	—	—	(2.5)
Other comprehensive income, net of tax	—	—	—	1.6	—	1.6
Net loss	—	—	—	—	(147.7)	(147.7)
Balance at June 30, 2024	67.1	0.1	2,863.9	(24.6)	334.1	3,173.5
Issuance of common stock under equity compensation plans	0.1	—	0.4	—	—	0.4
Stock-based compensation expense	—	—	12.0	—	—	12.0
Tax withholdings related to vesting of stock-based awards	—	—	(0.4)	—	—	(0.4)
Other comprehensive income, net of tax	—	—	—	21.1	—	21.1
Net loss	—	—	—	—	(19.9)	(19.9)
Balance at September 29, 2024	67.2	$ 0.1	$ 2,875.9	$ (3.5)	$ 314.2	$ 3,186.7

	Common Stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
	Shares	Par				
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	0.3	0.1	3.8	—	—	3.9
Stock-based compensation expense	—	—	10.4	—	—	10.4
Tax withholdings related to vesting of stock-based awards	(0.1)	—	(9.5)	—	—	(9.5)
Other comprehensive income, net of tax	—	—	—	8.3	—	8.3
Net income	—	—	—	—	48.8	48.8
Balance at April 2, 2023	66.6	0.1	2,809.0	(59.3)	2,246.7	4,996.5
Issuance of common stock under equity compensation plans	0.2	—	5.5	—	—	5.5
Stock-based compensation expense	—	—	13.7	—	—	13.7
Tax withholdings related to vesting of stock-based awards	—	—	(3.0)	—	—	(3.0)
Other comprehensive income, net of tax	—	—	—	43.0	—	43.0
Net loss	—	—	—	—	(53.2)	(53.2)
Balance at July 2, 2023	66.8	0.1	2,825.2	(16.3)	2,193.5	5,002.5
Issuance of common stock under equity compensation plans	—	—	0.8	—	—	0.8
Stock-based compensation expense	—	—	13.5	—	—	13.5
Tax withholdings related to vesting of stock-based awards	—	—	(0.5)	—	—	(0.5)
Other comprehensive loss, net of tax	—	—	—	(36.9)	—	(36.9)
Net loss	—	—	—	—	(12.7)	(12.7)
Balance at October 1, 2023	66.8	$ 0.1	$ 2,839.0	$ (53.2)	$ 2,180.8	$ 4,966.7

See accompanying notes.

QUIDELORTHO CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In millions)

	Nine Months Ended	
	September 29, 2024	October 1, 2023
OPERATING ACTIVITIES		
Net loss	$ (1,873.6)	$ (17.1)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	344.1	341.8
Goodwill impairment charge	1,743.9	—
Asset impairment charge	56.9	3.2
Stock-based compensation expense	32.5	39.3
Change in deferred tax assets and liabilities	(72.6)	(4.5)
Payment of accreted interest on deferred consideration	—	(9.7)
Other non-cash, net	(5.0)	(3.5)
Changes in assets and liabilities:		
Accounts receivable	7.6	124.1
Inventories	(110.9)	(146.0)
Prepaid expenses and other current and non-current assets	(23.5)	(35.1)
Accounts payable	(16.9)	(6.3)
Accrued payroll and related expenses	27.7	(31.0)
Income taxes payable	(80.5)	(51.3)
Other current and non-current liabilities	(10.4)	(4.1)
Net cash provided by operating activities	19.3	199.8
INVESTING ACTIVITIES		
Acquisitions of property, plant, equipment, investments and intangibles	(147.9)	(160.7)
Proceeds from government assistance allocated to fixed assets	—	10.5
Purchases of marketable securities	(7.2)	(50.6)
Proceeds from sale of marketable securities	63.1	68.3
Other payments	(20.0)	—
Net cash used for investing activities	(112.0)	(132.5)
FINANCING ACTIVITIES		
Proceeds from issuance of common stock	5.0	8.1
Short-term borrowings, net	(1.6)	2.9
Revolving credit facility, net	230.0	—
Payments on long-term borrowings	(107.0)	(175.7)
Payments of tax withholdings related to vesting of stock-based awards	(8.7)	(13.0)
Principal payments of deferred consideration	—	(30.3)
Net cash provided by (used for) financing activities	117.7	(208.0)
Effect of exchange rates on cash	(0.5)	(3.3)
Net increase (decrease) in cash, cash equivalents and restricted cash	24.5	(144.0)
Cash, cash equivalents and restricted cash at beginning of period	119.5	293.9
Cash, cash equivalents and restricted cash at end of period	$ 144.0	$ 149.9
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Purchase of property, equipment and intangibles by incurring current liabilities	$ 16.1	$ 11.4
Capital expenditures to be reimbursed under a government contract	$ —	$ 3.0
Transfer of instrument inventories to fixed assets	$ 99.4	$ 105.8
Reduction of accrued payroll and related expenses upon issuance of restricted share units	$ 0.3	$ 1.9
Initial recognition of finance lease right-of-use asset and liability	$ 12.5	$ —

See accompanying notes.

QuidelOrtho Corporation

Notes to Consolidated Financial Statements

(Unaudited)

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

Basis of Presentation

The accompanying unaudited Consolidated Financial Statements of QuidelOrtho Corporation and its subsidiaries (the "Company" or "QuidelOrtho") have been prepared in accordance with GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included. Refer to the Summary of Abbreviated Terms at the end of this Quarterly Report for definitions of terms used throughout the document.

The information at September 29, 2024, and for the three and nine months ended September 29, 2024 and October 1, 2023, is unaudited. For further information, refer to the Company's Consolidated Financial Statements and notes thereto for the fiscal year ended December 31, 2023 included in QuidelOrtho's Annual Report. Operating results for any quarter are historically seasonal in nature and are not necessarily indicative of the results expected for the full year.

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 2024 and 2023, the Company's fiscal year will end or has ended on December 29, 2024 and December 31, 2023, respectively. For 2024 and 2023, the Company's third quarter ended on September 29, 2024 and October 1, 2023, respectively. The three and nine months ended September 29, 2024 and October 1, 2023 each included 13 and 39 weeks, respectively.

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. 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 $2.2 million and $3.2 million recognized in the three and nine months ended October 1, 2023, respectively, related to impairment of long-lived assets from (i) Cost of sales, excluding amortization of intangibles (excludes $1.3 million and $1.4 million for the three and nine months ended October 1, 2023, respectively), and (ii) Research and development (excludes $0.9 million and $1.8 million for the three and nine months ended October 1, 2023, 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 Income (Loss), Consolidated Statements of Stockholders' Equity or Consolidated Statements of Cash Flows.

Recent Accounting Pronouncements

There have been no accounting pronouncements issued or adopted during the nine months ended September 29, 2024 that are expected to have a material impact on the Company's Consolidated Financial Statements.

Note 2. Computation of Earnings Per Share

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

	Three Months Ended		Nine Months Ended	
(In millions)	**September 29, 2024**	**October 1, 2023**	**September 29, 2024**	**October 1, 2023**
Basic weighted-average shares of common stock outstanding	67.3	66.9	67.1	66.8
Dilutive potential shares issuable from stock options and RSUs [(1)]	—	—	—	—
Diluted weighted-average shares of common stock outstanding	67.3	66.9	67.1	66.8

(1) In the three and nine months ended September 29, 2024 and October 1, 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:

	Three Months Ended		Nine Months Ended	
(In millions)	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Basic weighted-average shares of common stock outstanding	67.3	66.9	67.1	66.8
Dilutive potential shares issuable from stock options and RSUs	0.2	0.4	0.3	0.5
Diluted weighted-average shares of common stock outstanding	67.5	67.3	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 1.9 million and 2.0 million shares of common stock for the three and nine months ended September 29, 2024, respectively, and 1.7 million and 1.6 million shares of common stock for the three and nine months ended October 1, 2023, respectively.

Note 3. 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 September 29, 2024 and December 31, 2023 was $39.5 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 September 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 $39.5 million and $41.8 million as of September 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 September 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 the three and nine months ended September 29, 2024 and October 1, 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 $41.9 million and $36.8 million as of September 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 $17.4 million and $13.9 million as of September 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 the three and nine months ended September 29, 2024 was $4.8 million and $31.8 million, respectively.

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 $7.3 million and $24.3 million during the three and nine months ended September 29, 2024, respectively, and $8.9 million and $38.6 million during the three and nine months ended October 1, 2023, respectively. These amounts included the Company's portion of the pre-tax net profit of $5.3 million and $16.8 million during the three and nine months ended September 29, 2024, respectively, and $7.3 million and $14.0 million during the three and nine months ended October 1, 2023, 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. The Company's portion of the pre-tax net profit also included revenue from collaboration and royalty agreements of $2.0 million and $7.5 million during the three and nine months ended September 29, 2024, respectively, and $1.6 million and $24.6 million during the three and nine months ended October 1, 2023, respectively, which is presented on a net basis within Total revenues.

Disaggregation of Revenue

The following table summarizes Total revenues by business unit:

	Three Months Ended		Nine Months Ended	
(In millions)	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Labs	$ 355.9	$ 341.4	$ 1,067.0	$ 1,073.5
Immunohematology [1]	132.0	128.9	385.9	380.1
Donor Screening [1]	28.0	35.0	95.7	103.0
Point of Care	205.6	233.1	509.3	675.4
Molecular Diagnostics	5.6	5.6	17.2	23.2
Total revenues	$ 727.1	$ 744.0	$ 2,075.1	$ 2,255.2

(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 the nine months ended September 29, 2024, one customer represented 11% of Total revenues. For the nine months ended October 1, 2023, no customers individually accounted for more than 10% of Total revenues. Revenue related to the Company's respiratory products accounted for 23% and 17% of Total revenues for the three and nine months ended September 29, 2024, respectively, and 25% and 24% for the three and nine months ended October 1, 2023, respectively.

As of September 29, 2024 and December 31, 2023, customers with a balance due in excess of 10% of Accounts receivable, net totaled $ 63.0 million and $63.5 million, respectively.

Note 4. Segment and Geographic Information

The Company operates in three geographically-based reportable segments: North America, EMEA and China.

Effective January 1, 2024, Japan and Asia Pacific operating segments were combined into one operating segment: JPAC. The CODM reviews the Company's performance and allocates resources based on five operating segments: North America, EMEA, China, Latin America and 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."

Total revenues by reportable segment are as follows:

(In millions)	Three Months Ended		Nine Months Ended	
	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
North America	$ 436.2	$ 465.2	$ 1,220.2	$ 1,426.8
EMEA	84.0	74.5	249.9	236.4
China	80.4	81.1	238.1	233.0
Other	126.5	123.2	366.9	359.0
Total revenues	$ 727.1	$ 744.0	$ 2,075.1	$ 2,255.2

The following table sets forth Adjusted EBITDA by segment and the reconciliations to Loss before income taxes for the three and nine months ended September 29, 2024 and October 1, 2023:

(In millions)	Three Months Ended		Nine Months Ended	
	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
North America	$ 233.0	$ 253.4	$ 625.7	$ 708.1
EMEA	6.7	10.2	30.9	22.7
China	36.9	37.3	97.4	96.0
Other	31.7	31.2	97.8	89.3
Total segment Adjusted EBITDA	308.3	332.1	851.8	916.1
Corporate [1]	(137.6)	(162.9)	(459.2)	(388.3)
Depreciation and amortization	(113.1)	(113.1)	(344.1)	(341.8)
Interest expense, net	(42.9)	(37.7)	(122.9)	(110.9)
Integration related costs	(36.8)	(26.5)	(90.3)	(80.4)
Goodwill impairment charge	—	—	(1,743.9)	—
Asset impairment charge	—	(2.2)	(56.9)	(3.2)
Amortization of deferred cloud computing implementation costs	(4.7)	(2.8)	(10.6)	(5.9)
EU medical device regulation transition costs [2]	(0.4)	(0.4)	(1.5)	(1.9)
Loss on investments	—	(1.0)	—	(1.2)
Employee compensation charges	—	—	(5.6)	—
Credit Agreement amendment fees	—	—	(4.0)	—
Tax indemnification income	—	0.1	—	0.2
Other adjustments	(1.6)	(1.1)	(3.4)	(2.6)
Loss before income taxes	$ (28.8)	$ (15.5)	$ (1,990.6)	$ (19.9)

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

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

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

Note 5. Income Taxes

The Company calculates its interim income tax provision in accordance with ASC 270, *Interim Reporting*, and ASC 740, *Accounting for Income Taxes*. At the end of each interim period, the Company estimates its annual effective tax rate and applies that rate to its ordinary quarterly earnings to calculate the tax related to ordinary income. The tax effects for other items that are excluded from ordinary income are discretely calculated and recognized in the period in which they occur.

For the three months ended September 29, 2024, the Company recognized an income tax benefit of $ 8.9 million in relation to loss before income taxes of $28.8 million, resulting in an effective tax rate of 30.9%. For the three months ended October 1, 2023, the Company recognized an income tax benefit of $ 2.8 million in relation to loss before income taxes of $15.5 million, resulting in an effective tax rate of 18.1%. For the three months ended September 29, 2024, the effective tax rate differed from the U.S. federal statutory rate primarily due to the utilization of net operating losses previously not benefited due to valuation allowances. For the three months ended October 1, 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to net operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances and Global Intangible Low-Tax Income, partially offset by non-U.S. earnings being taxed at rates that were different than the U.S. statutory rate, R&D credits, foreign tax credits and foreign exchange losses.

For the nine months ended September 29, 2024, the Company recognized an income tax benefit of $ 117.0 million in relation to loss before income taxes of $1,990.6 million, resulting in an effective tax rate of 5.9%. For the nine months ended October 1, 2023, the Company recognized an income tax benefit of $2.8 million in relation to loss before income taxes of $ 19.9 million, resulting in an effective tax rate of 14.1%. For the nine months ended September 29, 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 the nine months ended October 1, 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to net operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances and Global Intangible Low-Tax Income, partially offset by non-U.S. earnings being taxed at rates that were different than the U.S. statutory rate, R&D credits, foreign tax credits and foreign exchange losses.

The balance of unrecognized tax benefits at September 29, 2024, not including interest and penalties, was $ 30.1 million, of which $22.6 million could affect the effective income tax rate in future periods, if recognized. The Company also recognizes interest and penalties related to unrecognized tax benefits in tax expense. At September 29, 2024, the Company had approximately $4.5 million of interest and penalties accrued related to unrecognized tax benefits. The Company estimates that within the next 12 months, its uncertain tax positions, excluding interest, should decrease by $11.7 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 2012 and onwards are subject to examination by the U.S. authorities. The Company's state and foreign tax years for 2001 and onwards are subject to examination by applicable tax authorities. The Company believes that it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax laws applied to the facts of each matter.

Indemnification Assets

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 are required to be indemnified by Johnson & Johnson. The indemnification receivable from Johnson & Johnson totaled $3.1 million and $3.0 million as of September 29, 2024 and December 31, 2023, respectively, and is included as a component of Prepaid expenses and other current assets on the Consolidated Balance Sheet.

Note 6. Balance Sheet Account Details

Cash, Cash Equivalents and Restricted Cash

(In millions)	September 29, 2024	December 31, 2023
Cash and cash equivalents	$ 143.7	$ 118.9
Restricted cash included in Other assets	0.3	0.6
Cash, cash equivalents and restricted cash	$ 144.0	$ 119.5

Marketable Securities

The Company had no marketable securities outstanding as of September 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)	September 29, 2024	December 31, 2023
Accounts receivable	$ 395.2	$ 395.1
Allowance for contract rebates and discounts	(86.6)	(77.2)
Allowance for doubtful accounts	(13.7)	(14.6)
Total accounts receivable, net	$ 294.9	$ 303.3

Inventories

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

(In millions)	September 29, 2024	December 31, 2023
Raw materials	$ 211.4	$ 212.7
Work-in-process (materials, labor and overhead)	92.4	92.3
Finished goods (materials, labor and overhead)	331.2	318.1
Total inventories	$ 635.0	$ 623.1
Inventories	$ 577.0	$ 577.8
Other assets [1]	58.0	45.3
Total inventories	$ 635.0	$ 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)	September 29, 2024	December 31, 2023
Income taxes and other tax receivables	$ 181.1	$ 104.7
Prepaid expenses	86.4	67.0
Contract assets	39.5	46.2
Other receivables	26.2	34.2
Derivatives	8.0	6.9
Other	3.0	3.1
Total prepaid expenses and other current assets	$ 344.2	$ 262.1

Other Current Liabilities

Other current liabilities consisted of the following:

(In millions)	September 29, 2024	December 31, 2023
Accrued commissions, rebates and returns	$ 59.9	$ 63.8
Accrued interest	45.5	30.3
Deferred revenue	41.9	36.8
Operating lease liabilities	31.3	26.7
Accrued other taxes payable	21.8	17.9
Derivatives	6.1	12.1
Other	84.9	115.7
Total other current liabilities	$ 291.4	$ 303.3

Note 7. Assets Held for Sale

The following criteria are considered before concluding assets are classified as held for sale: 1) management's commitment to a plan to sell, 2) availability for immediate sale in its present condition, 3) initiation of an active program to identify a buyer, 4) probability of a completed sale within one year, 5) actively marketed for sale at a reasonable price in relation to its current fair value, and 6) 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.

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 has 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.

Note 8. Goodwill and Intangible Assets, Net

Changes in goodwill were as follows:

(In millions)	North America	EMEA	China	Other	Total
Balance at December 31, 2023	$ 1,743.9	$ 582.4	$ 85.7	$ 80.0	$ 2,492.0
Impairment charge	(1,743.9)	—	—	—	(1,743.9)
Foreign currency translation	—	21.8	1.6	(0.9)	22.5
Balance at September 29, 2024	$ —	$ 604.2	$ 87.3	$ 79.1	$ 770.6

The Company tests goodwill for impairment on an annual basis on the first day of the fourth quarter and monitors throughout the year for impairment triggering events that indicate that the carrying value of one or more of its reporting units exceeds its fair value.

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.

The estimated fair values of the EMEA, Latin America and JPAC reporting units as of the interim testing 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) ranged from approximately 30% to 150%. 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, Latin America and JPAC reporting units, the Company applied a hypothetical 5% decrease to the fair values of each reporting unit and compared those hypothetical values to the reporting unit carrying values. Based on this hypothetical 5% decrease, the excess of the estimated fair value over carrying value (expressed as a percentage of carrying value for the respective reporting unit) for each of the Company's reporting units ranged from approximately 25% to 140%.

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 of 2024, the Company tested its North America long-lived asset group for recoverability and impairment as of March 31, 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 long-lived asset group were above the carrying value and the Company determined that the long-lived asset group was recoverable, and no impairment existed as of March 31, 2024. Subsequent to the first quarter of 2024, no impairment indicators were noted.

Note 9. Borrowings

The components of borrowings were as follows:

(In millions)	September 29, 2024	December 31, 2023
Term Loan	$ 2,317.1	$ 2,420.2
Revolving Credit Facility	230.0	—
Financing lease obligation	9.3	0.4
Other short-term borrowings	—	1.6
Other long-term borrowings	0.1	0.4
Unamortized deferred financing costs	(6.1)	(8.0)
Total borrowings	2,550.4	2,414.6
Less: current portion	(373.8)	(139.8)
Long-term borrowings	$ 2,176.6	$ 2,274.8

The Credit Agreement, dated May 27, 2022, by and among the Company, as borrower, Bank of America, N.A., as administrative agent and swing line lender, and the other lenders and L/C issuers party thereto 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 $230.0 million borrowings outstanding, was $557.0 million as of September 29, 2024. During the nine months ended September 29, 2024, the Company made $103.1 million in payments on the Term Loan.

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 (the “Amendment”), by and among the Company, the lenders party thereto, and Bank of America, N.A., as administrative agent, which amends the Credit Agreement. 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 September 29, 2024.

The following table provides the detailed amounts within Interest expense, net for the three and nine months ended September 29, 2024 and October 1, 2023:

	Three Months Ended		Nine Months Ended	
(In millions)	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Term Loan	$ 43.9	$ 45.7	$ 132.8	$ 130.8
Revolving Credit Facility	5.6	0.9	10.8	1.9
Amortization of deferred financing costs	0.8	0.9	2.4	2.5
Derivative instruments and other	(7.0)	(8.5)	(21.3)	(20.2)
Interest income	(0.4)	(1.3)	(1.8)	(4.1)
Interest expense, net	$ 42.9	$ 37.7	$ 122.9	$ 110.9

Note 10. Stock-based Compensation

Stock-based compensation expense was as follows:

	Three Months Ended		Nine Months Ended	
(In millions)	September 29, 2024	October 1, 2023	September 29, 2024	October 1, 2023
Cost of sales, excluding amortization of intangibles	$ 1.4	$ 1.2	$ 4.1	$ 3.3
Selling, marketing and administrative	9.2	10.3	21.0	27.5
Research and development	0.7	1.6	2.6	4.2
Integration related costs	1.2	4.0	5.1	13.1
Total stock-based compensation expense	$ 12.5	$ 17.1	$ 32.8	$ 48.1

The table above includes compensation expense related to liability-classified awards of $ 3.0 million and $8.8 million for the three and nine months ended October 1, 2023, respectively, which has been or is expected to be settled in cash. Amounts related to the three and nine months ended September 29, 2024 were not material.

Note 11. Commitments and Contingencies

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-MKV (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 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 Company’s Board of Directors and three of its 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-MKV (S.D.N.Y.) (the “Whitfield Complaint”), and Steven Pinkney v. Douglas Bryant, et al., Case No. 1:24-cv-4753-MKV (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.

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 other litigation and legal proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to its business. The Company accrues for legal claims when, and to the extent that, amounts associated with the claims become probable and are reasonably estimable. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded. Estimates of probable losses resulting from these matters are inherently difficult to predict. The actual costs of resolving legal claims may be substantially higher or lower than the amounts accrued for those claims. For those matters as to which the Company is not able to estimate a possible loss or range of loss, the Company is not able to determine whether the loss will have a material adverse effect on its business, financial condition, results of operations or liquidity.

Management believes that all such current legal actions, in the aggregate, are not expected to have a material adverse effect on the Company. However, the resolution of, or increase in any accruals for, one or more matters may have a material adverse effect on the Company’s results of operations and cash flows.

Note 12. 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:

	September 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	—	10.3	—	10.3	—	6.9	—	6.9
Total assets measured at fair value	$ —	$ 10.3	$ —	$ 10.3	$ —	$ 62.7	$ —	$ 62.7
Liabilities:								
Derivative liabilities	$ —	$ 47.1	$ —	$ 47.1	$ —	$ 27.5	$ —	$ 27.5
Contingent consideration	—	—	—	—	—	—	0.1	0.1
Total liabilities measured at fair value	$ —	$ 47.1	$ —	$ 47.1	$ —	$ 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 the nine months ended September 29, 2024 and fiscal year 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 $ 2,293.9 million at September 29, 2024, compared to the carrying amount, excluding debt issuance costs, of $2,317.1 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 13. 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 9. 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 loss of $1.3 million as of September 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 September 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

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, Euro, Indian Rupee, Japanese Yen, Mexican Peso, Philippine Peso, South Korean Won, 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 gains of $2.2 million as of September 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 September 29, 2024:

Description	Notional Amount (In millions)	Hedge Designation
Foreign currency forward contracts	$ 188.7	Cash Flow Hedge
Foreign currency forward contracts	$ 833.6	Non-designated

The following table summarizes pre-tax gains and losses from designated derivative and non-derivative instruments within AOCI for the three and nine months ended September 29, 2024 and October 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
Three Months Ended September 29, 2024			
Foreign currency forward contracts (sales)	$ 3.2	Total revenues	$ —
Foreign currency forward contracts (purchases)	$ (0.1)	Cost of sales, excluding amortization of intangibles	$ 0.3
Interest rate derivatives	$ 41.7	Interest expense, net	$ (7.1)
Nine Months Ended September 29, 2024			
Foreign currency forward contracts (sales)	$ (2.8)	Total revenues	$ 2.1
Foreign currency forward contracts (purchases)	$ 0.7	Cost of sales, excluding amortization of intangibles	$ 0.3
Interest rate derivatives	$ (4.1)	Interest expense, net	$ (21.3)
Three Months Ended October 1, 2023			
Foreign currency forward contracts (sales)	$ (1.0)	Total revenues	$ 1.8
Foreign currency forward contracts (purchases)	$ (0.1)	Cost of sales, excluding amortization of intangibles	$ 0.4
Interest rate derivatives	$ (28.0)	Interest expense, net	$ (8.5)
Nine Months Ended October 1, 2023			
Foreign currency forward contracts (sales)	$ 0.7	Total revenues	$ 2.7
Foreign currency forward contracts (purchases)	$ (2.2)	Cost of sales, excluding amortization of intangibles	$ 2.1
Interest rate derivatives	$ (54.1)	Interest expense, net	$ (21.1)

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 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
Three Months Ended September 29, 2024		
Foreign exchange contracts	$ 20.2	$ (3.3)
Nine Months Ended September 29, 2024		
Foreign exchange contracts	$ 1.9	$ (8.2)

Fair value gains and losses on foreign currency forward contracts, as determined using Level 2 inputs, that do not qualify for hedge accounting treatment are recorded in Other expense, net. Fair value gains were $4.4 million and $10.1 million for the

three and nine months ended September 29, 2024, respectively. Fair value losses that do not qualify for hedge accounting treatment were $ 0.2 million for the three months ended October 1, 2023 and fair value gains were $0.3 million for the nine months ended October 1, 2023.

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

(In millions)	September 29, 2024	December 31, 2023
Designated cash flow hedges		
Interest rate derivatives:		
Prepaid expenses and other current assets	$ 2.3	$ 0.2
Other liabilities	24.1	6.9
Foreign currency forward contracts:		
Prepaid expenses and other current assets	2.1	3.2
Other assets	2.3	—
Other current liabilities	4.3	9.4
Other liabilities	16.9	8.5
Non-designated hedging instruments		
Foreign currency forward contracts:		
Prepaid expenses and other current assets	3.6	3.5
Other current liabilities	1.8	2.7

Note 14. Accumulated Other Comprehensive Loss

The following table summarizes the changes in AOCI by component:

	Three Months Ended September 29, 2024				
(In millions)	Pension and Other Post-Employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income
Balance at June 30, 2024	$ (1.3)	$ 21.7	$ —	$ (45.0)	$ (24.6)
Current period deferrals [1]	—	(33.7)	—	64.9	31.2
Amounts reclassified to Net loss	—	(6.8)	—	(3.3)	(10.1)
Net change	—	(40.5)	—	61.6	21.1
Balance at September 29, 2024	$ (1.3)	$ (18.8)	$ —	$ 16.6	$ (3.5)

	Nine Months Ended September 29, 2024				
(In millions)	Pension and Other Post-Employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income
Balance at December 31, 2023	$ (1.3)	$ (9.8)	$ —	$ (18.9)	$ (30.0)
Current period deferrals [1]	—	9.9	—	43.7	53.6
Amounts reclassified to Net loss	—	(18.9)	—	(8.2)	(27.1)
Net change	—	(9.0)	—	35.5	26.5
Balance at September 29, 2024	$ (1.3)	$ (18.8)	$ —	$ 16.6	$ (3.5)

(In millions)	Three Months Ended October 1, 2023				
	Pension and Other Post-Employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income
Balance at July 2, 2023	$ 0.7	$ 14.6	$ (0.4)	$ (31.2)	$ (16.3)
Current period deferrals [2]	—	24.5	0.2	(55.3)	(30.6)
Amounts reclassified to Net loss	—	(6.3)	—	—	(6.3)
Net change	—	18.2	0.2	(55.3)	(36.9)
Balance at October 1, 2023	$ 0.7	$ 32.8	$ (0.2)	$ (86.5)	$ (53.2)

(In millions)	Nine Months Ended October 1, 2023				
	Pension and Other Post-employment Benefits	Cash Flow Hedges	Available-for-Sale Investments	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income
Balance at January 1, 2023	$ 0.7	$ 1.5	$ (0.5)	$ (69.3)	$ (67.6)
Current period deferrals [2]	—	47.6	0.3	(17.2)	30.7
Amounts reclassified to Net loss	—	(16.3)	—	—	(16.3)
Net change	—	31.3	0.3	(17.2)	14.4
Balance at October 1, 2023	$ 0.7	$ 32.8	$ (0.2)	$ (86.5)	$ (53.2)

(1) Includes tax impact of (i) $11.1 million and $3.7 million related to cash flow hedges for the three and nine months ended September 29, 2024, respectively, and (ii) $1.9 million and $2.0 million related to foreign currency translation adjustments for the three and nine months ended September 29, 2024, respectively.

(2) Includes tax impact of $4.6 million and $8.0 million related to cash flow hedges for the three and nine months ended October 1, 2023, respectively.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

In this Quarterly Report, all references to "we," "our" and "us" refer to QuidelOrtho Corporation and its subsidiaries.

Future Uncertainties and Forward-Looking Statements

This Quarterly 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 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," including under "Outlook" and "Liquidity Outlook," and located elsewhere herein regarding our commercial, integration and other strategic goals, our cost-savings initiatives, industry prospects, our expected results of operations or financial position, and future plans, objectives, strategies, expectations and intentions. Without limiting the foregoing, the words "may," "will," "would," "should," "might," "expect," "anticipate," "believe," "estimate," "plan," "intend," "goal," "project," "strategy," "future," "continue" or similar words, expressions or the negative of such terms or other comparable terminology are intended to identify forward-looking statements. Such statements are based on the beliefs and expectations of our management as of the date of this Quarterly 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 II, Item 1A, "Risk Factors" of this Quarterly Report and Part I, Item 1A, "Risk Factors" of our 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 Quarterly Report. We undertake no obligation to update any of the forward-looking information or time-sensitive information included in this Quarterly Report, whether as a result of new information, future events, changed expectations or otherwise, except as required by law.

Information Available on Our Website

This Quarterly 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 Quarterly Report or filed with or furnished to the SEC and should not be considered part of this Quarterly 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, Immunohematology, Donor Screening, Point of Care and Molecular Diagnostics.

For the nine months ended September 29, 2024, Total revenues decreased by 8% to $2,075.1 million as compared to the same period in the prior year, primarily driven by variability of our U.S. respiratory products. Currency exchange rates had an unfavorable impact of 100 basis points on our growth rate. Our revenues can be highly concentrated over a small number of products, including certain of our respiratory products. For the nine months ended September 29, 2024 and October 1, 2023, revenues related to our respiratory products accounted for approximately 17% and 24% 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 ORTHO VERSEIA® Integrated Processor 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 the prior year periods, contributed to the decline in revenue with a margin lower than our overall margin. Refer to Item 1, "Financial Statements—Note 3. 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.

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.

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. As a result, we expect to continue to maintain our emphasis on R&D investments for longer term growth, including for our next generation platforms and assays, as well as additional assays to be launched on our current platforms. In addition, we expect to continue to evaluate strategic opportunities to (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.

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.

Results of Operations

Revenues

The following table compares Total revenues by business unit for the three and nine months ended September 29, 2024 and October 1, 2023:

	Three Months Ended			Nine Months Ended		
(Dollars in millions)	September 29, 2024	October 1, 2023	% Change	September 29, 2024	October 1, 2023	% Change
Labs	$ 355.9	$ 341.4	4 %	$ 1,067.0	$ 1,073.5	(1) %
Immunohematology [1]	132.0	128.9	2 %	385.9	380.1	2 %
Donor Screening [1]	28.0	35.0	(20) %	95.7	103.0	(7) %
Point of Care	205.6	233.1	(12) %	509.3	675.4	(25) %
Molecular Diagnostics	5.6	5.6	— %	17.2	23.2	(26) %
Total revenues	$ 727.1	$ 744.0	(2) %	$ 2,075.1	$ 2,255.2	(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 the three months ended September 29, 2024, Total revenues decreased to $727.1 million from $744.0 million for the same period in the prior year. Labs revenue increased 4% compared to the prior year period, primarily due to growth in recurring revenue, which includes reagents, consumables and services in our Labs revenue, partially offset by a decline in instrument revenue. Excluding foreign currency impact, Labs revenue increased 5% compared to the prior year period. Immunohematology revenue increased 2% compared to the prior year period, primarily due to reagent growth. Donor Screening revenue decreased 20% compared to the prior year period, primarily due to the wind-down of the U.S. donor screening business. Point of Care revenue decreased 12% compared to the prior year period, primarily due to lower sales of Sofia SARS Antigen assays, partially offset by an increase in demand for QuickVue SARS Antigen assays. Currency exchange rates did not significantly impact our growth rate for the three months ended September 29, 2024.

For the nine months ended September 29, 2024, Total revenues decreased to $2,075.1 million from $2,255.2 million for the same period in the prior year. Labs revenue decreased 1% compared to the prior year period, primarily due to a $19.2 million settlement award from a third party related to one of our collaboration agreements in the prior year period, partially offset by growth in recurring revenue. Immunohematology revenue increased 2% compared to the prior year period, primarily due to reagent growth. Donor Screening revenue decreased 7% 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 $178.9 million in sales of QuickVue SARS Antigen assays, primarily due to a COVID-19 government award in the prior year period, partially offset by an increase of $11.8 million in sales of Sofia SARS Antigen assays. Molecular Diagnostics sales decreased by $6.0 million, driven primarily by lower demand. Currency exchange rates had an unfavorable impact of approximately 100 basis points on our growth rate for the nine months ended September 29, 2024.

Cost of Sales, Excluding Amortization of Intangible Assets

Cost of sales, excluding amortization of intangible assets, increased to $374.8 million, or 51.5% of Total revenues, for the three months ended September 29, 2024, compared to $374.6 million, or 50.3% of Total revenues, for the three months ended October 1, 2023. Cost of sales, excluding amortization of intangible assets, was impacted by a shift in product mix.

Cost of sales, excluding amortization of intangible assets, decreased to $1,114.7 million, or 53.7% of Total revenues, for the nine months ended September 29, 2024, compared to $1,140.7 million, or 50.6% of Total revenues, for the nine months ended October 1, 2023. The decrease in cost of sales, excluding amortization of intangible assets, was driven primarily by a prior year period COVID-19 government award, along with the corresponding inventory release of $39 million, partially offset by an increase in sales of Sofia SARS Antigen assays.

Operating Expenses

The following table summarizes operating expenses for the three and nine months ended September 29, 2024 and October 1, 2023:

	Three Months Ended				Nine Months Ended			
(Dollars in millions)	September 29, 2024	% of Total Revenues	October 1, 2023	% of Total Revenues	September 29, 2024	% of Total Revenues	October 1, 2023	% of Total Revenues
Selling, marketing and administrative	$ 186.4	25.6 %	$ 194.1	26.1 %	$ 579.3	27.9 %	$ 575.6	25.5 %
Research and development	55.9	7.7 %	61.5	8.3 %	171.4	8.3 %	185.7	8.2 %
Amortization of intangible assets	51.9	7.1 %	51.4	6.9 %	155.5	7.5 %	153.6	6.8 %
Integration related costs	36.8	5.1 %	26.5	3.6 %	90.3	4.4 %	80.4	3.6 %
Goodwill impairment charge	—	N/M	—	N/M	1,743.9	N/M	—	N/M
Asset impairment charge	—	N/M	2.2	N/M	56.9	N/M	3.2	N/M
Other operating expenses	6.3	0.9 %	7.4	1.0 %	23.6	1.1 %	17.0	0.8 %

* N/M - Not meaningful

Selling, Marketing and Administrative Expenses

Selling, marketing and administrative expenses for the three months ended September 29, 2024 decreased by $7.7 million, or 4.0%, to $186.4 million from $194.1 million for the same period in the prior year, primarily due to lower employee compensation costs.

Selling, marketing and administrative expenses for the nine months ended September 29, 2024 increased by $3.7 million, or 0.6%, to $579.3 million from $575.6 million for the same period in the prior year, primarily due to higher employee compensation costs.

Research and Development Expense

Research and development expense for the three months ended September 29, 2024 decreased by $5.6 million, or 9.1%, to $55.9 million from $61.5 million for the same period in the prior year, primarily due to lower outside services and employee compensation costs.

Research and development expense for the nine months ended September 29, 2024 decreased by $14.3 million, or 7.7%, to $171.4 million from $185.7 million for the same period in the prior year, primarily due to lower employee compensation costs and outside services.

Amortization of Intangible Assets

Amortization of intangible assets was $51.9 million and $155.5 million for the three and nine months ended September 29, 2024, respectively, and $51.4 million and $153.6 million for the three and nine months ended October 1, 2023, respectively.

Integration Related Costs

Integration related costs were $36.8 million and $90.3 million for the three and nine months ended September 29, 2024, respectively, and $26.5 million and $80.4 million for the three and nine months ended October 1, 2023, respectively. The increase in costs compared to the prior year periods was primarily due to consulting costs and employee compensation related charges.

Goodwill Impairment Charge

During the nine months ended September 29, 2024, we identified a triggering event requiring an interim goodwill impairment assessment for our reporting units. As a result, we recognized a non-cash goodwill impairment charge of $1.7 billion for the North America reporting unit. Refer to Item 1, “Financial Statements—Note 8. Goodwill and Intangible Assets, Net” for more information.

Asset Impairment Charge

During the nine months ended September 29, 2024, we recognized an impairment charge of $56.9 million related to the long-lived assets classified as assets held for sale. Refer to Item 1, “Financial Statements—Note 7. Assets Held for Sale” for more information. Asset impairment charges were $2.2 million and $3.2 million for the three and nine months ended October 1, 2023, respectively.

Other Operating Expenses

Other operating expenses were $6.3 million and $23.6 million for the three and nine months ended September 29, 2024, respectively, and $7.4 million and $17.0 million for the three and nine months ended October 1, 2023, respectively. Other operating expenses were primarily related to the profit share expense for our Joint Business with Grifols.

Non-operating Expenses

Interest Expense, Net

Interest expense, net was $42.9 million and $122.9 million for the three and nine months ended September 29, 2024, respectively, and $37.7 million and $110.9 million for the three and nine months ended October 1, 2023, respectively. Refer to Item 1, “Financial Statements—Note 9. Borrowings” for more information.

Other Expense, Net

Other expense, net was $0.9 million and $7.2 million for the three and nine months ended September 29, 2024, respectively, and $4.1 million and $8.0 million for the three and nine months ended October 1, 2023, respectively. The decreases from prior year periods were primarily related to net foreign currency losses offset by the Credit Agreement amendment fees. Refer to Item 1, “Financial Statements—Note 9. Borrowings” for more information.

Income Taxes

For the three months ended September 29, 2024, we recognized an income tax benefit of $8.9 million in relation to loss before income taxes of $28.8 million, resulting in an effective tax rate of 30.9%. For the three months ended October 1, 2023, we recognized an income tax benefit of $2.8 million in relation to loss before income taxes of $15.5 million, resulting in an effective tax rate of 18.1%. For the three months ended September 29, 2024, the effective tax rate differed from the U.S. federal statutory rate primarily due to the utilization of net operating losses previously not benefited due to valuation allowances. For the three months ended October 1, 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to net operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances and Global Intangible Low-Tax Income, partially offset by non-U.S. earnings being taxed at rates that were different than the U.S. statutory rate, R&D credits, foreign tax credits and foreign exchange losses.

For the nine months ended September 29, 2024, we recognized an income tax benefit of $117.0 million in relation to loss before income taxes of $1,990.6 million, resulting in an effective tax rate of 5.9%. For the nine months ended October 1, 2023, we recognized an income tax benefit of $2.8 million in relation to loss before income taxes of $19.9 million, resulting in an effective tax rate of 14.1%. For the nine months ended September 29, 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 the nine months ended October 1, 2023, the effective tax rate differed from the U.S. federal statutory rate primarily due to net operating losses in certain subsidiaries not being benefited due to the establishment of valuation allowances and Global Intangible Low-Tax Income, partially offset by non-U.S. earnings being taxed at rates that were different than the U.S. statutory rate, R&D credits, foreign tax credits and foreign exchange losses.

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.”

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 before Interest expense, net, Benefit from 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 and that we do not consider indicative of our ongoing operating performance. Refer to Item 1, “Financial Statements—Note 4. Segment and Geographic Information” for a reconciliation of Adjusted EBITDA by reportable segment to Loss before income taxes.

North America

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

	Three Months Ended			Nine Months Ended		
(Dollars in millions)	September 29, 2024	October 1, 2023	% Change	September 29, 2024	October 1, 2023	% Change
Total revenues	$ 436.2	$ 465.2	(6) %	$ 1,220.2	$ 1,426.8	(14) %
Adjusted EBITDA	$ 233.0	$ 253.4	(8) %	$ 625.7	$ 708.1	(12) %

Total revenues were $436.2 million for the three months ended September 29, 2024, compared to $465.2 million for the three months ended October 1, 2023. The decrease was primarily driven by lower revenues for Sofia SARS Antigen assays and the wind-down of the U.S. donor screening business, partially offset by higher demand for QuickVue SARS Antigen assays.

Total revenues were $1,220.2 million for the nine months ended September 29, 2024, compared to $1,426.8 million for the nine months ended October 1, 2023. The decrease was primarily driven by a COVID-19 government award in the prior year period and the wind-down of the U.S. donor screening business, partially offset by an increase in revenues for Sofia SARS Antigen assays.

Adjusted EBITDA was $233.0 million for the three months ended September 29, 2024, compared to $253.4 million for the three months ended October 1, 2023. The decrease was primarily driven by lower revenues for Sofia SARS Antigen assays and

the wind-down of the U.S. donor screening business, partially offset by a decrease in employee compensation costs, lower other operating expenses and higher demand for QuickVue SARS Antigen assays.

Adjusted EBITDA was $625.7 million for the nine months ended September 29, 2024, compared to $708.1 million for the nine months ended October 1, 2023. The decrease was primarily driven by a COVID-19 government award in the prior year period, along with the corresponding inventory release of $39 million, partially offset by a decrease in employee compensation costs, lower other operating expenses and an increase in revenues for Sofia SARS Antigen assays.

EMEA

Total revenues and Adjusted EBITDA for EMEA were as follows:

	Three Months Ended			Nine Months Ended		
(Dollars in millions)	September 29, 2024	October 1, 2023	% Change	September 29, 2024	October 1, 2023	% Change
Total revenues	$ 84.0	$ 74.5	13 %	$ 249.9	$ 236.4	6 %
Adjusted EBITDA	$ 6.7	$ 10.2	(34) %	$ 30.9	$ 22.7	36 %

Total revenues were $84.0 million for the three months ended September 29, 2024, compared to $74.5 million for the three months ended October 1, 2023, primarily driven by an increase in Labs and Immunohematology revenues.

Total revenues were $249.9 million for the nine months ended September 29, 2024, compared to $236.4 million for the nine months ended October 1, 2023, primarily driven by an increase in Labs and Immunohematology revenues.

Adjusted EBITDA was $6.7 million for the three months ended September 29, 2024, compared to $10.2 million for the three months ended October 1, 2023. The decrease was primarily driven by (i) product mix and (ii) foreign exchange net losses resulting from re-measurement and settlement transactions, including loans transacted in non-functional currencies. These decreases were partially offset by (i) an increase in Labs and Immunohematology revenues and (ii) net gains realized on foreign currency forward contracts.

Adjusted EBITDA was $30.9 million for the nine months ended September 29, 2024, compared to $22.7 million for the nine months ended October 1, 2023, primarily driven by an increase in Labs and Immunohematology revenues and product mix.

China

Total revenues and Adjusted EBITDA for China were as follows:

	Three Months Ended			Nine Months Ended		
(Dollars in millions)	September 29, 2024	October 1, 2023	% Change	September 29, 2024	October 1, 2023	% Change
Total revenues	$ 80.4	$ 81.1	(1) %	$ 238.1	$ 233.0	2 %
Adjusted EBITDA	$ 36.9	$ 37.3	(1) %	$ 97.4	$ 96.0	1 %

Total revenues were $80.4 million for the three months ended September 29, 2024, which decreased slightly compared to $81.1 million for the three months ended October 1, 2023, driven by an increase of 6% in Labs revenues, offset by decreases in other business units revenues.

Total revenues were $238.1 million for the nine months ended September 29, 2024, compared to $233.0 million for the nine months ended October 1, 2023, driven by an increase of 7% in Labs revenues, offset by decreases in other business units revenues.

Adjusted EBITDA was $36.9 million for the three months ended September 29, 2024, compared to $37.3 million for the three months ended October 1, 2023. The decrease was primarily driven by a decrease in other business units revenues, partially offset by higher Labs revenues.

Adjusted EBITDA was $97.4 million for the nine months ended September 29, 2024, compared to $96.0 million for the nine months ended October 1, 2023. The increase was primarily driven by higher Labs revenues, partially offset by a decrease in other business units revenues and the impact from changes in product mix.

Other

Total revenues and Adjusted EBITDA for Other were as follows:

(Dollars in millions)	Three Months Ended			Nine Months Ended		
	September 29, 2024	October 1, 2023	% Change	September 29, 2024	October 1, 2023	% Change
Total revenues	$ 126.5	$ 123.2	3 %	$ 366.9	$ 359.0	2 %
Adjusted EBITDA	$ 31.7	$ 31.2	2 %	$ 97.8	$ 89.3	10 %

Total revenues were $126.5 million for the three months ended September 29, 2024, which increased slightly compared to $123.2 million for the three months ended October 1, 2023, primarily due to an increase in Labs revenues, partially offset by a decrease in Point of Care revenues.

Total revenues were $366.9 million for the nine months ended September 29, 2024, compared to $359.0 million for the nine months ended October 1, 2023, primarily driven by an increase in Labs revenues, partially offset by a decrease in Point of Care revenues.

Adjusted EBITDA was $31.7 million for the three months ended September 29, 2024, which increased slightly compared to $31.2 million for the three months ended October 1, 2023. The increase was primarily driven by an increase in Labs revenues, partially offset by a decrease in Point of Care revenues and product mix.

Adjusted EBITDA was $97.8 million for the nine months ended September 29, 2024, compared to $89.3 million for the nine months ended October 1, 2023, primarily driven by an increase in Labs revenues, partially offset by a decrease in Point of Care revenues and product mix.

Liquidity and Capital Resources

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

(Dollars in millions)	September 29, 2024	December 31, 2023
Cash and cash equivalents	$ 143.7	$ 118.9
Marketable securities, current	—	48.4
Marketable securities, non-current	—	7.4
Total cash, cash equivalents and marketable securities	$ 143.7	$ 174.7
Amount available to borrow under the Revolving Credit Facility	$ 557.0	$ 787.1
Working capital including cash and cash equivalents and marketable securities, current	$ 385.3	$ 476.7

As of September 29, 2024, we had $143.7 million in Cash and cash equivalents, a $24.8 million increase 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 $230.0 million borrowings outstanding, was $557.0 million as of September 29, 2024.

On April 25, 2024, we entered into the Amendment, by and among us, the lenders party thereto, and Bank of America, N.A., as administrative agent, which amended the Credit Agreement. 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 September 29, 2024.

Capital Expenditures

Capital expenditures, including investments, were $147.9 million for the nine months ended September 29, 2024. We continue to make capital expenditures in connection with the expansion of our manufacturing capabilities and other facility-related activities.

Cash Flow Summary

	Nine Months Ended	
(In millions)	**September 29, 2024**	**October 1, 2023**
Net cash provided by operating activities	$ 19.3	$ 199.8
Net cash used for investing activities	(112.0)	(132.5)
Net cash provided by (used for) financing activities	117.7	(208.0)
Effect of exchange rates on cash	(0.5)	(3.3)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 24.5	$ (144.0)

Nine Months Ended September 29, 2024

Cash provided by operating activities was $19.3 million for the nine months ended September 29, 2024, and reflected a net loss of $1,873.6 million and non-cash adjustments of $2,099.8 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 $110.9 million cash outflows for inventories.

Cash used for investing activities was $112.0 million for the nine months ended September 29, 2024, and was primarily related to $147.9 million in purchases of property, plant, equipment, investments and intangibles. We also sold $63.1 million of marketable securities.

Cash provided by financing activities was $117.7 million for the nine months ended September 29, 2024, and was primarily related to net proceeds from the Revolving Credit Facility of $230.0 million, partially offset by payments on long-term borrowings of $107.0 million.

Nine Months Ended October 1, 2023

Cash provided by operating activities was $199.8 million for the nine months ended October 1, 2023, and reflected a net loss of $17.1 million and non-cash adjustments of $366.6 million, primarily associated with depreciation and amortization, stock-based compensation expense and accretion of interest on deferred consideration. We benefited from collections on accounts receivables of $124.1 million, primarily due to a COVID-19 government award, offset by other changes in working capital, including $146.0 million cash outflows for inventories.

Cash used for investing activities was $132.5 million for the nine months ended October 1, 2023, and was primarily related to $160.7 million in purchases of property, plant, equipment, investments and intangibles. We also purchased $50.6 million and sold $68.3 million of marketable securities.

Cash used for financing activities was $208.0 million for the nine months ended October 1, 2023, and was primarily related to payments on long-term borrowings of $175.7 million, payments for deferred consideration of $30.3 million and payments of tax withholdings related to vesting of stock-based awards of $13.0 million.

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 the nine months ended September 29, 2024, we transferred $99.4 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.

On March 1, 2024, our lease for warehouse space in the U.S. commenced. Information regarding the lease is included in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Recent Accounting Pronouncements

There have been no accounting pronouncements issued or adopted during the nine months ended September 29, 2024 that are expected to have a material impact on the Company's financial statements.

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.

A comprehensive discussion of our critical accounting estimates is included in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report. Other than the following, there have been no significant changes to our critical accounting policies and estimates during the nine months ended September 29, 2024:

Goodwill Impairment

We test goodwill for impairment on an annual basis on the first day of the fourth quarter and monitor throughout the year for impairment triggering events that indicate that the carrying value of one or more of our reporting units exceeds its fair value.

During the first quarter of 2024, we concluded that (i) the sustained decline in our 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 our interim goodwill impairment assessment in the first quarter of 2024, we concluded that the North America reporting unit’s carrying value exceeded its estimated fair value. As a result, we 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.

The estimated fair values of our EMEA, Latin America and JPAC reporting units as of the interim testing 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) ranged from approximately 30% to 150%. 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, Latin America and JPAC reporting units, we applied a hypothetical 5% decrease to the fair values of each reporting unit and compared those hypothetical values to the reporting unit carrying values. Based on this hypothetical 5% decrease, the excess of the estimated fair value over carrying value (expressed as a percentage of carrying value for the respective reporting unit) for each of our reporting units ranged from approximately 25% to 140%.

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.

We believe 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.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in our exposure to market risk from that described in “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report.

ITEM 4. 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). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of September 29, 2024 at a reasonable assurance level to ensure that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Changes in internal control over financial reporting: There were no changes in our internal control over financial reporting during the fiscal quarter ended September 29, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

The information set forth in Part I—Financial Information, Item 1, “Financial Statements—Note 11. Commitments and Contingencies” is incorporated herein by reference.

ITEM 1A. Risk Factors

There has been no material change in our risk factors as previously disclosed in our Annual Report. For a detailed description of our risk factors, refer to Part I, Item IA, “Risk Factors” of our Annual Report.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

On August 17, 2022, our Board of Directors 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 through the expiration date.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

(a) None.

(b) None.

(c) 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 (within the meaning of SEC rules).

ITEM 6. Exhibits

Exhibit Number	
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 filed on February 23, 2023)
4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-Q filed on August 5, 2022)
31.1*	Certification by Principal Executive Officer of QuidelOrtho Corporation pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification by Principal Financial Officer of QuidelOrtho Corporation pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications by Principal Executive Officer and Principal Financial Officer of QuidelOrtho Corporation pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial statements, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Loss, (iii) Consolidated Statements of Comprehensive Income (Loss), (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, formatted in Inline XBRL (included as Exhibit 101)

* Filed herewith.

** Furnished herewith.

SUMMARY OF ABBREVIATED TERMS

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

Annual Report	Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as amended by Amendment No. 1 to the Annual Report
AOCI	Accumulated other comprehensive loss
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CODM	Chief Operating Decision Maker
Combinations	Business combination consummated by Quidel and Ortho on May 27, 2022, pursuant to a 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.
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
EBITDA	Earnings before interest, taxes, depreciation and amortization
EMEA	Europe, the Middle East and Africa
EPS	Loss per share
Exchange Act	Securities Exchange Act of 1934, as amended
GAAP	Generally accepted accounting principles in the U.S.
Grifols	Grifols Diagnostic Solutions, Inc.
IT	Information technology
Joint Business	Ongoing collaboration arrangement between Ortho and Grifols
JPAC	Japan and Asia Pacific
OCI	Other comprehensive income (loss)
Ortho	Ortho Clinical Diagnostics Holdings plc
Quarterly Report	Quarterly Report on Form 10-Q for the quarter ended September 29, 2024
Quidel	Quidel Corporation
R&D	Research and development
Revolving Credit Facility	$800.0 million revolving credit facility under the Credit Agreement
RSU	Restricted stock unit
RSV	Respiratory syncytial virus
SEC	Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
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.S.	United States
USD	United States dollar

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 7, 2024

QUIDELORTHO CORPORATION

/s/ BRIAN J. BLASER

Brian J. Blaser

President and Chief Executive Officer
(Principal Executive Officer)

/s/ JOSEPH M. BUSKY

Joseph M. Busky

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Brian J. Blaser, certify that:

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

Date: November 7, 2024

/s/ BRIAN J. BLASER

Brian J. Blaser

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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

I, Joseph M. Busky, certify that:

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

Date: November 7, 2024

/s/ JOSEPH M. BUSKY

Joseph M. Busky

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

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

- the Company's Quarterly Report on Form 10-Q for the period ended September 29, 2024 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2024

/s/ BRIAN J. BLASER

Brian J. Blaser

President and Chief Executive Officer

(Principal Executive Officer)

/s/ JOSEPH M. BUSKY

Joseph M. Busky

Chief Financial Officer

(Principal Financial Officer)